

A Dissertation On
TO EVALUATE THE EFFICACY OF COLD HIP BATH IN PRIMARY
DYSMENORRHOEA

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The Institutional Ethical Committee of Government Yoga & Naturopathy Medical College and Hospital, Chennai reviewed and discussed the application for approval of **“TO EVALUATE THE EFFICACY OF COLD HIP BATH IN PRIMARY DYSMENORRHOEA”**, project work submitted by Dr.P.Prema latha, 2nd year M.D.Naturopathy, Post graduate, Government Yoga and Naturopathy Medical College and Hospital, Chennai.

The proposal is APPROVED.

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LIST OF ABBREVIATIONS USED

CHB	Cold Hip Bath
VAS	Visual Analogue Scale
MSQ	Menstrual Symptom Questionnaire
NPI	Numeric Pain Scale
BMI	Body Mass Index
PP	Pulse Rate
RR	Respiratory Rate
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
SD	Standard Deviation
NSAID	Non-Steroidal Anti Inflammatory Drugs
CCPP	Chronic Cyclical Pelvic Pain
OCP	Oral Contraceptive Pills
TENS	Transcutaneous Electrical Nerve Stimulation
NCCAM	National Centre For Complementary And Alternative Medicine
CE	Cold Exposure
COX	Cyclooxygenase
SHBG	Sex Hormone Binding Globulin

TXA2	Thromboxane A2
ACTH	Adrenocorticotrophic Hormone
CRH	Corticotrophic Hormone
TSS	Toki-Shakuyaku-San
LUNA	Laparoscopic Uterine Nerve Ablation
CAM	Complementary And Alternative Medicine
HRQoL	Health-Related Quality Of Life

ABSTRACT

Objective: To evaluate the efficacy of cold hip bath on primary dysmenorrhoea.

Dysmenorrhoea is a common gynecological problem in women of reproductive age.

Many studies have stated that Yoga and Naturopathy has a positive impact on primary dysmenorrhoea. The present study was conducted to evaluate the cold hip bath alone is able to reduce the pain in primary dysmenorrhoea.

Study Design: A Randomised control trial

Methodology:

60 subjects of age group between 16 -25 years who were diagnosed with primary dysmenorrhoea participated in the study. After getting informed consent from the patient Menstrual symptom questionnaire(MSQ), Visual analogue Scale (VAS) will be given for all participants to score dysmenorrhoea-related symptoms. The cold hip bath treatment duration 8 minutes at 55 -65 ° F will be given from the sixth day of menstrual period to the next menstrual cycle. After intervention (MSQ) and (VAS) will be given for all participants .

Result: There was significant reduction ($P<0.05$) in the intensity of pain in primary dysmenorrhoea during the subsequent visit. The spasmodic and congestive components of primary dysmenorrhoea was also reduced ($P<0.05$) significantly.

Conclusion: The study suggest that Cold hip bath may help to reduce the intensity of pain and improve the symptoms in primary dysmenorrhoea.

KEYWORDS: Menstrual symptom questionnaire(MSQ), Visual analogue Scale (VAS)

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INTRODUCTION

The onset of puberty in the life of a young girl sets into motion hormonal, psychological, cognitive and physical changes which transforms the girl from a child to a sexually matured woman.¹

Menstruation is a normal physiological process that occurs approximately once in a month in women of reproductive age which is controlled by the hormones of the hypothalamopituitary axis, involves the cyclical shedding of the inner lining of the uterus as a result of the breakdown of the endometrial tissue.^{2,3}

Menstrual disorders are commonly present in late adolescence.⁴

Dysmenorrhoea is a common health problem in women of reproductive age and it is characterized by severe uterine pain during menstruation,⁵ and it is one of the most common causes of pelvic pain and menstrual disorder.⁵



Figure:1 Dysmenorrhoea

The International Association for the Study of Pain defines pain as “an unpleasant sensory ,emotional experience associated with actual or potential tissue damage, or described in terms of such damage”⁶. In particular, chronic cyclical pelvic pain(CCPP) is located in the pelvic area and lasts for 6 months or longer⁷. Thus, the World Health Organization estimated that dysmenorrhea is the most important cause of chronic cyclical pelvic pain(CCPP)⁸

Dysmenorrhoea may be categorized into two distinct types: primary and secondary. Primary dysmenorrhoea is defined as painful menses in women with normal pelvic anatomy and normal physiology, usually beginning during adolescence. The onset of primary dysmenorrhoea usually starts 6 to 12 months after menarche, which coincides with the occurrence of regular ovulatory cycles.⁹

The Primary dysmenorrhoea is an important clinical as well as social problem affecting more than 50% of menstruating women.¹⁰

A recent systematic review of the world literature on prevalence of dysmenorrhoea varies widely across the world ranging from 15 to 94%.^{10, 11,13,14}

The Prevalence of dysmenorrhoea in india was 70.2%.¹⁵

Dysmenorrhoea has different harmful effects on individuals and the community. For instance, school and work absenteeism, interference with daily living activities, limitation in socialization, and higher intake of sedative medications are positively associated with the higher prevalence and intensity of dysmenorrhoea.^{8,16}

Dysmenorrhoea affects the physical, psychological, social status of female adolescents.¹⁷

The etiology of primary dysmenorrhoea is not precisely understood but most symptoms can be cleared by the action of uterine prostaglandins, particularly PGF2 α . The disintegrating endometrial cells release PGF2 α as menstruation begins. PGF2 α will stimulates myometrial contractions,

ischemia and sensitization of nerve endings. These levels are highest during the first two days of menses when symptoms peak.¹⁸

There are two types of primary dysmenorrhoea, Spasmodic and congestive. The spasmodic type refers to spasms of pain that are similar to labor pains. They usually start during the first day of menstruation. The congestive type of dysmenorrhoea refers to a variation or a symptom of the premenstrual syndrome accompanied with dull aching pain, lethargy and depression prior to the onset of menstruation.¹⁹

Childbirth, in contrast, appears to relieve dysmenorrhoea.²⁰

Dysmenorrhoea is a very common problem among girls and it affects their quality of life. It can be better managed by mental preparation and by appropriate change in lifestyle like regular physical exercise and will give hope to the students. It is important to spread awareness about the causes and treatment of dysmenorrhoea to avoid unnecessary sufferings causing absenteeism from work and studies.²¹

An experimental study conducted in Iran showed that regular physical activity reduced the dysmenorrhoea.²²

NSAIDs and Oral contraceptive pills (OCP) are used as a common treatment for dysmenorrhoea, which can be reduced the myometrical activity.²³

The Complementary and alternative medical treatments for primary dysmenorrhoea will include transcutaneous electric nerve stimulation(TENS), acupuncture, acupressure, behavioral intervention, spinal manipulation, relaxation and dietary therapies. Few studies have also examined the result of life style modification intervention in management of dysmenorrhea.²⁴

The National Centre for Complementary and Alternative Medicine (NCCAM) refers yoga as —mind-body medicine, which is being recommended as a non-pharmacological tool for managing a variety of non-communicable diseases.^{25,26}

Yoga includes various postures (Asanas), breathing techniques (Pranayama), and meditation has been shown to have therapeutic benefits for the individuals with disease conditions, including hypertension and diabetes.^{27,28}

Naturopathy is a system of man building in harmony with a constructive principles of nature cure on physical, mental , moral and spiritual planes of being and consist of non-invasive treatment modalities like diet therapy, fasting therapy, yoga therapy ,mud therapy, hydrotherapy, massage, acupuncture,chromo therapy and magneto therapy²⁹

Hydrotherapy is one of the naturopathy treatment .The external or internal use of water with various temperatures, pressure, duration, and site

and different modes of application in any of its forms (water, ice, steam) for health promotion or treatment of various diseases .It is one of the naturopathic treatment modality which was used widely in ancient cultures including India, Egypt, China, etc.³⁰

The first ultimate treatise on hydrotherapy explaining its techniques and effects was written by John Harvey Kellogg in 1900 entitled “Rational Hydrotherapy”.³¹

Naturopathic procedures mainly help to improve blood circulation to the reproductive organs and thereby relieve the congestion. The treatment used for the Dysmenorrhoea include Revulsive compress over pelvic region, Neutral Hip Bath, Revulsive Hip Bath, Mud pack to abdomen, Abdominal pack etc. depending upon the type of Dysmenorrhea.³²

The warm water sitz bath is well known as a safe and low morbidity method of management for anorectal and gynecologic conditions.^{33,34} Most physicians, including colon and rectal surgeons, suggest warm sitz baths to relieve pain in the perineal region and to promote wound healing, even though there is no rational clarification for this maneuver.³⁵

The Warm sitz baths SB (40-45°C) for 10 min, for at least 5 days immediately after removal of Foley urethral catheter in patients

undergone transurethral resection of prostate, considerably reduced postoperative complications such as urethral stricture³⁶

Cold-SB but not warm-SB, significantly reduced edema during the postepisiotomy period.³⁷

Thirty healthy volunteers and 21 patients with urinary retention after hemorrhoidectomy undergone SB at 40°C, 45°C, and 50°C where the number of spontaneous micturitions increased with higher-temperature baths and it seems to be initiated by reflex (thermo-sphincter reflex) internal urethral sphincter relaxation.

The urethral pressure both in normal and retention subjects showed that significant reduction, which increased with higher temperature; and vesical pressure or EMG activity of the external urethral sphincter did not show significant differences.³⁸

Succeeding CE exercise in water (18°C) induced immune-stimulating effects.³⁹

During CE increase levels of circulating norepinephrine was observed³⁹ and exercising HPA system by repeated CE could restore its normal function in chronic fatigue syndrome, or at least increase in net HPA activity (without changing baseline activity).⁴⁰ It produces temporary increase in the plasma levels of adrenocorticotrophic hormone (ACTH), beta-endorphin, and cortisol.⁴¹

The constant/longer-term effects of cold stress repeated daily gives increase in ACTH, corticosterone, and decrease in α -1-antitrypsin and testosterone.⁴² The Cold stress reduces level of serotonin in most parts of brain (except brainstem).⁴¹ Cold stress-induced analgesia might be mediated by increased production of opioid peptide beta-endorphin (an endogenous pain-killer).⁴³

CE can activate the mechanism of reticular activating system such as locus coruleus and raphe nuclei, which can result in activation of behavior and increased capacity of central nervous system (CNS) to recruit motoneurons.⁴¹

CE activates SNS; increase blood level of beta-endorphin and noradrenaline; and increase synaptic release of noradrenaline in brain. The Antidepressive effect of cold shower attributed to presence of high density of cold receptors in skin estimated to send an overwhelming amount of electrical impulses from peripheral nerve endings to the brain. It has considerable analgesic effect and it does not cause dependence or noticeable side effects.⁴⁴

Exposure to cold increases MR, for example, head-out immersion in cold water of 20°C almost doubles MR, while at 14°C it is more than quadrupled.⁴⁵

Immersion at 20°C produced similar decrease in plasma renin activity, HR, SBP, and DBP, in spite of lowered Tre and increased MR by 93%. The Plasma cortisol concentrations tended to decrease, while plasma aldosterone concentration was unchanged.⁴⁵

Cold exposure (CE) to the small surface area produced compensatory vasodilatation in deeper vascular system resulting in increased blood flow to the tissues underlying the area of exposure. This vascular reaction occurs mainly to maintain constant deep tissue temperature.⁴⁶

Eventhough many countries used water to produce different physiological or therapeutic effects on different part of the system for maintaining the health, preventing, and treating the diseases, the scientific evidence-based effects of cold hip bath are not well documented.

With such profound effects on the body hydrotherapy alone has the ability to bring about physiological changes in the body. Hence the present study was aimed to evaluate the effects of cold hip bath on primary dysmenorrhoea. In Naturopathic medicines studies related to the physiological effects of treatment modalities are less. It is essential to understand the underlying mechanisms before applying them as therapeutic agent .

2.0 AIMS AND OBJECTIVES

2.1 AIMS:

The purpose of the study is to evaluate the efficacy of cold hip bath on primary dysmenorrhoea. It was hypothesized that the cold hip bath will help to reduce the pain in primary dysmenorrhoea.

2.2 OBJECTIVES:

□ □ To assess the Visual analogue scale (VAS) before the intervention in primary dysmenorrhoea subjects.

□ □ To assess the Visual analogue scale (VAS) after the intervention and compare the in Visual analogue scale (VAS) primary dysmenorrhoea subjects.

□ □ To assess the Modified Menstrual Symptoms Questionnaire before and after the intervention in primary dysmenorrhoea subjects.

3.0 REVIEW OF LITERATURE

3.1 MENSTRUATION:

Menstruation is a normal physiological process that occurs approximately once in a month in women of reproductive age which is controlled by the hormones of the hypothalamopituitary axis, involves the cyclical shedding of the inner lining of the uterus as a result of the breakdown of the endometrial tissue.^{2,3}

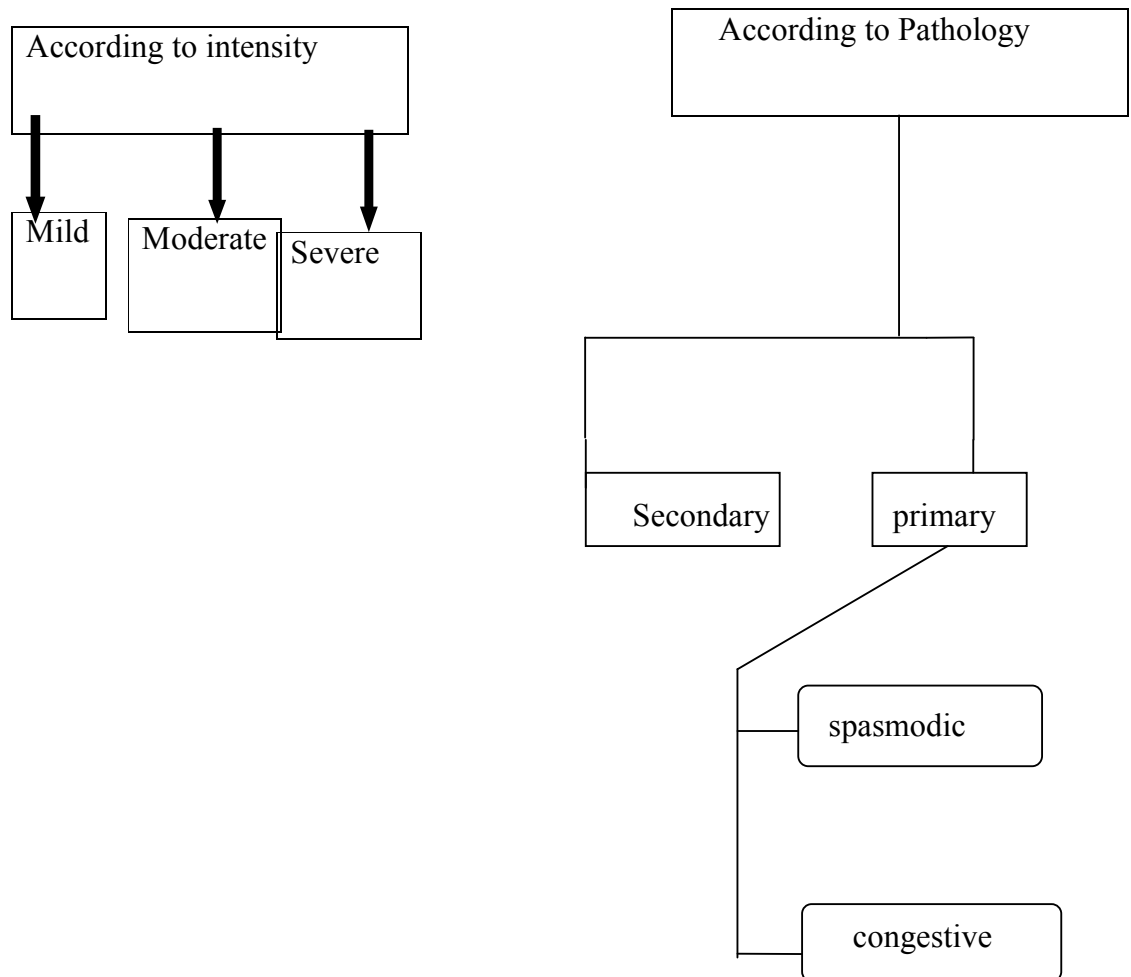
3.2 DYSMENORRHOEA:

“Dysmenorrhoea” is derived from a Greek word means difficult menstrual flow. The term dysmenorrhoea refers to painful menstruation. Dysmenorrhoea or painful menstruation is defined as a severe, painful, cramping sensation in the lower abdomen that is often accompanied by other symptoms, such as sweating, headaches, nausea, vomiting, diarrhea, and tremulousness, all occurring just before or during the menses.⁴⁸

Dysmenorrhoea, which is characterized by crampy pelvic pain beginning shortly before or at the onset of menses and lasting for 1–3 days.⁴⁹ The Pain duration is commonly 8–72 hours which is usually associated with the onset of menstrual flow and adolescent girls tend to have a higher prevalence of primary dysmenorrhoea than older women, as primary dysmenorrhoea can improve with age.⁵⁰

There are 2 types of dysmenorrhea: Primary dysmenorrhea and secondary dysmenorrhoea

Figure 2: Classification of Dysmenorrhoea



3.3. SECONDARY DYSMENORRHEA:

Secondary dysmenorrhoea is caused by underlying pelvic pathology and is more common in women more than 20 years.⁵¹

Secondary dysmenorrhoea occurs in association with some sort of pelvic pathology:

- It will occur years after onset of menstruation.
- The pain can precede the start of the period by several days and may last throughout the period.
- There may be associated dyspareunia.
- Secondary dysmenorrhoea may occurs due to:
 - Endometriosis/adenomyosis.
 - Pelvic inflammatory disease.
 - Fibroids, often associated with heavy menstrual bleeding.
 - Adhesions.
 - Developmental abnormalities.
- The copper-containing intrauterine contraception device (Cu-IUCD) may cause pelvic pain in the first few months after fitting but does not influence the severity of dysmenorrhoea in longer term.⁵²

3.4 PRIMARY DYSMENORRHEA:

Primary dysmenorrhoea refers to pain with no pathological pelvic disease and almost always first occurs in women 20 years or younger after their ovulatory cycles become established.⁴⁸

3.4.1 TYPES OF PRIMARY DYSMENORRHEA:

Dysmenorrhoea has been classified into following types:

3.4.1.1 Congestive Dysmenorrhoea: In this type, the pain starts between three and five days before onset of menstruation. It is often relieved by starting of menstrual flow. The causes of this type of dysmenorrhoea may or may not be associated to any underlying disease of pelvic area. It is often corrected by modifications in diet, treatment of constipation and implementation of exercise in case of sedentary workers.⁵³

3.4.1.2 Spasmodic Dysmenorrhoea: This is commonest type of dysmenorrhoea. Almost all females suffer from this type of dysmenorrhoea at some point of their life. The pain develops on the first day of menstrual period. The pain is severe, intermittent and spasm like in nature. If severe, it may cause nausea, vomiting, faintness or collapse. Often, severe episode of pain is followed by a phase of less severe pain in abdomen, pelvic area or

front of thighs. The spasmodic type of dysmenorrhoea pain lasts for around 12 hours.⁵³

3.4.1.3 Membranous Dysmenorrhoea: This type of dysmenorrhoea is rare and has a genetic disposition. The pain is associated with passage of membranes which resemble uterine endometrium microscopically.⁵³

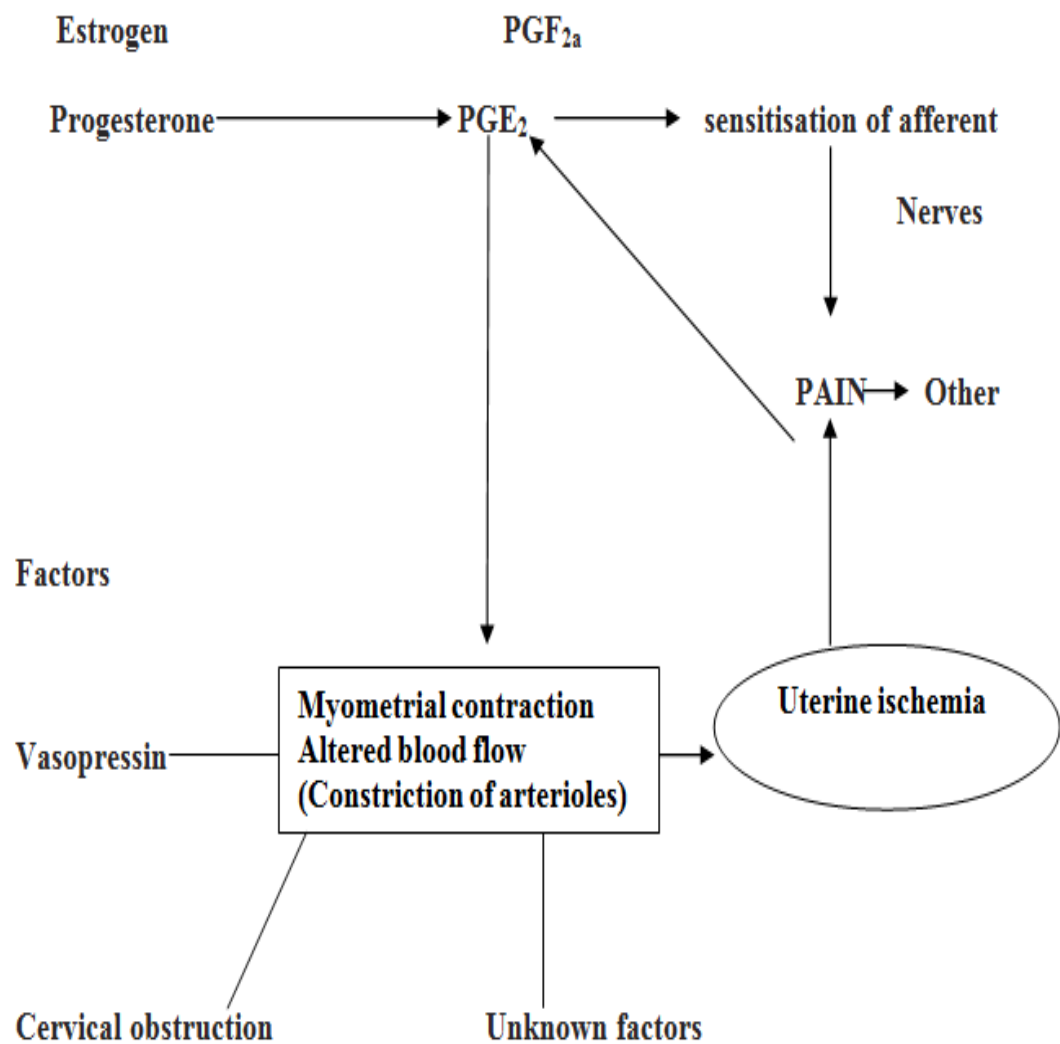
3.4.1.4 Ovarian Dysmenorrhoea: In this type of dysmenorrhoea, the pain is felt for two to three days before menstruation in right or left lower abdominal or pelvic areas.⁵³

3.4.2 CAUSES FOR DYSMENORRHOEA:

The primary causes for primary dysmenorrhoea are behavioral and psychological factors, uterine ischemia, cervical stenosis or narrowing, increased vasopressin release, increased uterine activity, and increased uterine prostanoid production. Evidence suggests that most women with primary dysmenorrhoea have increased or abnormal uterine prostanoid production and release, it leads to rise in abnormal uterine activity and therefore give rise to pain.⁵⁴⁻⁵⁹

Vasopressin also plays a role in increasing the uterine contractility and causing ischemic pain as a result of vasoconstriction. Elevated vasopressin levels are seen in women with primary dysmenorrhoea.⁶⁰

Figure 3: Causes for primary Dysmenorrhea



During menstruation in the non-dysmenorrhoeic woman, the uterine resting tone is lowest (<10 mm Hg), the active pressure is maximum (120 mm Hg), and the number of contractions (3 to 4 per 10 minutes) is least, compared with the rest of the cycle.^{54,55,61-63}

In dysmenorrhoeic women, the increased release of uterine prostaglandins causes a significant degree of myometrial hyperactivity that results in uterine hypoxia and ischemia. Four different types of abnormalities of uterine contraction have been observed in women with primary dysmenorrhoea, including increased uterine resting tone, increased active pressure, increased number of contractions, and in coordinate or dysrhythmic uterine activity. Most patients with primary dysmenorrhoea appear to have increased uterine resting tone. When these uterine contraction abnormalities are present, they tend to potentiate each other, and pain occurs with a much smaller change in the abnormality than when only one is present. When the uterine activity is abnormal and increased, uterine blood flow has been shown to be reduced. Once the uterine blood flow is enhanced the symptoms will disappear.

In women with primary dysmenorrhoea, the endometrial tissues are capable of increased production and the release of prostaglandins during

menstruation. Pickles et al⁶⁴ were the first to quantitate prostaglandins in menstrual fluid and demonstrate that dysmenorrheic women produce 8 to 13 times more prostaglandin F than nondysmenorrheic women. Most of the production and release of prostaglandins occurs during the first 48 hours of menstrual flow, leads to intense pain experienced during the first or second day of menstruation in primary dysmenorrhoea. Luteal-phase human endometrium from dysmenorrheic women has been shown *in vitro* to produce seven times more prostaglandin F_{2α} than luteal phase endometrium of normal women.⁶⁵

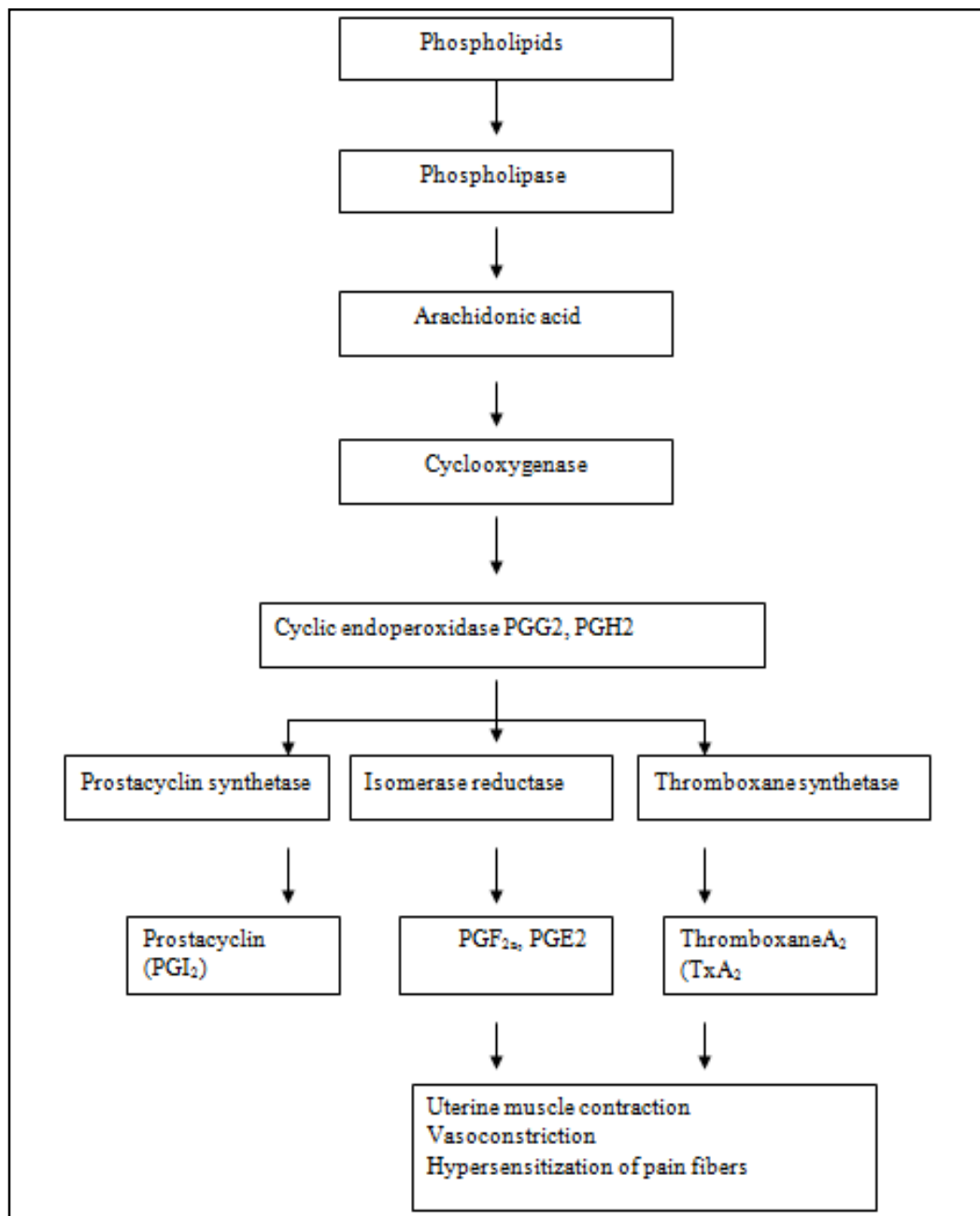
The roles of prostanoids, such as thromboxane A₂ and prostacyclin, and leukotrienes in primary dysmenorrhoea are not clearly understood. The Preliminary evidence suggests that prostacyclin is involved in the pathophysiology of primary dysmenorrhea.⁶⁶

Increased uterine leukotriene may be responsible for primary dysmenorrhea.⁶⁷ that do not respond to the therapy with nonsteroidal anti-inflammatory drugs, because leukotrienes are produced through the 5-lipoxygenase enzyme pathway rather than the cyclooxygenase pathway. Prostacyclin, which is a potent vasodilator that relaxes uterine muscle *in vitro*. A reduction of prostacyclin may potentiate enhancement of uterine activity and vasoconstriction, which gives rise to hypoxia, ischemia, and pain. In some women, an imbalance in the concentrations of different prostaglandins increases or decreases may be responsible for the pain.

Prostaglandins and prostanoids are biosynthesized from arachidonic acid through the COX pathway after production of arachidonic acid from hydrolysis of phospholipids by phospholipase. When pregnancy does not occur, progesterone levels decline during the late luteal phase. This causes labilization of lysosomes and release of their phospholipase enzyme, which then hydrolyzes the cell membrane phospholipids to generate arachidonic acid as well as icosatetraenoic acid. These compounds then serve as the precursors for the COX and lipoxygenase pathways.⁶⁸

The arachidonic acid cascade showing the cyclooxygenase (COX) pathway, the biosynthesis of cyclic endoperoxides PGG and PGH, and the final products: prostacyclin, prostaglandins F (PGF) and E (PGE), and thromboxane A₂ (TxA₂). Thus, COX inhibitors block early in the COX pathway. Prostaglandin F, PGE, and TxA induce smooth muscle contractions (uterine contractility, Vasoconstriction and hypersensitization of pain nerve fibers).

Figure 4: The arachidonic acid cascade showing the cyclooxygenase (COX) pathway



In fact a certain amount of body fat appears to be important to maintain normal ovulatory cycles with both too much and too little fat being associated with the disruption of their reproductive health.^{69,70} There are several known mechanisms which influence the adipose tissue on ovulation and menstrual cycle: 1) adipose tissue converts androgens to oestrogen by aromatisation; 2) body weight influences direction of oestrogen metabolism with very thin women making less potent and obese women more potent forms of oestrogen; 3) obese women have a diminished capacity for the oestrogen to bind to sex-hormone binding globulin (SHBG) which inactivates the oestrogen, resulting in an elevated percentage of free serum oestradiol.⁷¹

There is a suggestion that endometrial thickness may be influenced by adiposity through its oestrogen-mediated effect.^{72,73} Body weight has been inversely related with serum SHBG concentrations⁷⁴ and diminished SHBG or increased serum oestrogen potentially increases oestrogenic stimulation of the endometrium, prompting proliferation of tissues that produce prostaglandins, particularly $\text{PGF}_{2\alpha}$.⁷⁵ However an inverse relationship was shown between BMI and total oestrogen⁷⁶ supporting the theory that oestrogen/progesterone ratio, instead of oestrogen alone, may underlie the pathogenesis of dysmenorrhoea.⁷⁷

Alternatively, adipose tissue produces adipokines, the signalling molecules which will vary in their production with adipose mass and may directly cause impaired ovarian function through altering the hypothalamic-pituitary-ovarian axis signalling, resulting in disrupted menstruation.⁷² There is evidence that menstrual irregularity is higher in both girls with low and high BMI^{78,71} and having menstrual irregularity has been associated with dysmenorrhoea.⁷⁹

3.4.2.1 HYPOTHALAMUS - PITUITARY – OVARIAN AXIS:

The hypothalamus-pituitary-ovarian axis controls menstrual rhythm. Hypothalamus is connected with the cerebrum and limbic system which is the site for emotions and also to the pituitary gland by portal circulation. Stressful events like anxiety and depression causes emotional response that disturbs the HPO axis. Psychological stressors can directly increase the inflammatory mediators which is the main cause for pain during menstruation.⁸⁰

3.4.2.2 STRESS AND IT'S RELATION WITH DYSMENORRHOEA:

The observed association between stress and dysmenorrhoea is biologically believable although the biological mechanism(s) that link stress

to dysmenorrhoea are completely understood. When persons are under internal or external stress, they undergo a cascade of neuroendocrine responses. Corticotrophin releasing hormone (CRH), the major hypothalamic regulator of the mammalian stress response, mediates pituitary adrenocorticotrophic hormone (ACTH) secretion; the latter will enhance adrenal cortisol secretion.^{81,82} Stress is also known to inhibit the pulsatile release of follicle stimulating hormone and luteinising hormone, leading to impaired follicular development.⁸³ Because the synthesis of progesterone is increased in the luteinised follicle following ovulation, stress induced impairment of follicular development could potentially alter progesterone synthesis and release. Progesterone is thought to play an important role in dysmenorrhoea. Menstrual pain occurs only in ovulatory cycles, and progesterone has been shown to affect both the synthesis of prostaglandins PGF_{2a} and PGE₂ and the binding of these prostaglandins to myometrial receptors.⁸⁴ Prostaglandins affect uterine muscle and vascular tone,⁸⁵⁻⁸⁸ and an imbalance of prostaglandins has been associated to the occurrence of dysmenorrhoea.⁸⁴ In addition progesterone, stress related hormones, including adrenaline^{84,82,89} and cortisol,^{90,91} also appear to influence prostaglandin synthesis, which suggests that stress may have both direct and secondary effects on prostaglandin concentrations in the myometrium.

There are evidence showed a connection between psychosocial induced stress and menses-associated health problem, suggesting that stress may affect menstrual function.⁷⁸

3.4.2.3 OESTROGEN RELATIONS:

In addition, there is an evidence that ovarian hormones (especially oestrogens) play a role in modulating the range of chronic pain conditions through affecting concentration of oestrogen receptors in the spinal cord or the corresponding brain regions, or through interacting with the different neurotransmitters that modulate pain perception.⁹² Generally a low oestrogen milieu is recommended to exacerbate the severity of chronic pain ⁹²which may be particularly relevant in the connection between underweight and dysmenorrhoea.

3.4.2.4 LIFE STYLE MODIFICATION :

Due to today's sedentary lifestyle and lack of exercise, the problem of dysmenorrhoea is becoming a major problem throughout the world which causes discomfort for women's every day activities and this is the major contributing factor in absent for work or school and inability to participate in sports or other activities.⁹³ The discomforts that accompany

menstruation exist due to our lifestyle choices and this can be prevented and cured without the use of hormones and toxic medication.⁹⁴ It is generally accepted that a combination of psychological and organic approach should help in curing primary dysmenorrhoea. (Paulson and Wood, 1966).

Ebru Dikensoy et al 2008, conducted a study on Malondialdehyde, nitric oxide and adrenomedullin levels in patients with primary dysmenorrhoea. The results of this study showed that the serum levels of MDA, NO, and AM increase in subjects with primary dysmenorrhoea and this suggests that the possibility that lipid peroxidation and oxidative stress may have a significant role in the etiopathogenesis of primary dysmenorrhea.⁹⁵

The epidemiologic study of dysmenorrhoea among Japanese adolescents showed that sports activity levels, short sleeping hours, and skipping breakfast (marginal significance) were associated with dysmenorrhoea in this population. Dysmenorrhoea which adversely affects the daily activities is highly prevalent, and may be related with lifestyle factors among female junior high school students.⁹⁶

3.4.3 ASSESSMENT

A presumptive diagnosis of primary dysmenorrhoea may be made on history, abdominal examination alone in young patients who are

not sexually active, and vaginal examination is not normally required in this group of patients.

Investigation of dysmenorrhoea is primarily aimed at ruling out underlying pathology and may include any or all of the following as suitable to the individual.

3.4.3.1History

- Age at menarche.
- Whether the cycle is regular.
- Cycle length.
- Timing of pain in relation to period.
- Duration of bleeding.
- Location of pain. Dysmenorrhoea is usually suprapubic but it may be felt in the back of the legs or lower back
- Obstetric history.
- Contraceptive history.
- Smoking history.
- Whether the patient is sexually active.

- Any features indicated for underlying pathology (eg, vaginal discharge, intermenstrual or postcoital bleeding, dyspareunia).
- Dyschezia and/or rectal pain or bleeding - particularly indicative for endometriosis.
- The physical examination is totally normal, and the menstrual pain may be associated with systemic symptoms, such as nausea, vomiting, diarrhea, fatigue, fever, headache, and insomnia.⁹⁷⁻⁹⁹ There is no evidence for routine use of ultrasound in evaluation of primary dysmenorrhea, although ultrasound is very useful in excluding secondary causes of dysmenorrhea, such as endometriosis and adenomyosis.¹⁰⁰

3.4.3.2 DIAGNOSIS OF PRIMARY DYSMENORRHEA:

The Diagnostic criteria of primary dysmenorrhoea are subjective. Two tools are commonly used to measure the severity of dysmenorrhoea. The first is a verbal multidimensional pain scoring system helps to measure the pain severity and also the impacts of pain on daily activities, systemic symptoms and analgesic requirements.

3.4.3.3 Multidimensional Scoring System

The Intensity of pain was assessed by the Multidimensional Scoring System of Andersch and Milsom¹⁰¹ (1982) which defines pain as follows:

- Mild dysmenorrhea is defined as painful menstruation with no restraint of normal activity, with infrequent requirement of analgesics and no systemic complaints.
- Moderate dysmenorrhea is defined as menstrual pain which affects daily activities, with requirement of analgesics for pain relief and few systemic complaints.
- Severe dysmenorrhea is defined as menstrual pain with severe restraint of daily activities, poor response to analgesics, and apparent systemic complaints like vomiting, fainting etc.

3.4.3.4 Visual Analogue Scale (VAS)

The second system depends on asking the patient to assess the severity of dysmenorrhoea and express it on a linear Visual Analogue Scale (VAS). This scale is a 10 cm line drawn on a sheet of paper. It represents a continuum of severity of pain starting with the extreme of “no pain” and ending with the extreme of “unbearable pain.”¹⁰²

3.4.3.3 DIFFERENTIAL DIAGNOSIS:

The differential diagnosis of primary dysmenorrhea are secondary dysmenorrhea, Chronic pelvic inflammatory disease such as Pelvic adhesions, Irritable bowel syndrome, Inflammatory bowel disease, Interstitial cystitis etc. Sudden onset of dysmenorrhea might be seen in ectopic pregnancy or Spontaneous abortion.⁵²

3.4.4 RISK FACTORS:

The risk factors for dysmenorrhoea are Younger age, low body mass index, low family income, living in a rural area, smoking, early menarche, prolonged and heavier menstrual flow, higher in coffee consumers, nulliparity , premenstrual somatic complaints, pelvic infections, genetic influence, stress and depression.^{103,104}

3.4.5 PREVALANCE OF DYSMENORRHEA:

Dysmenorrhoea is the common gynaecological symptom reported by women. Ninety percent of the women presenting for primary care suffer from some menstrual pain.¹⁰⁵

A recent systematic review of the world literature on chronic cyclical pelvic pain reports prevalence of dysmenorrhoea ranging between 17% and 80%.¹⁰⁶ A dysmenorrhoea prevalence of 33.5% among adolescent girls in India was reported by the Nag.¹⁰⁷ George and Bhaduri identified dysmenorrhoea to be a common problem in India with prevalence of 87.7%.¹⁰⁸ There had been some studies in India from New Delhi, Wardha, Gwalior, Andhra Pradesh, Karnataka, Tamilnadu, and Gujarat stated that the prevalence rate of dysmenorrhoea as 33%, 56%, 79.67%, 65%, 67.5%, 76.30% and 45% respectively. The Prevalence rates of dysmenorrhoea were found to be 72.7% in Turkey, 74.5% in Malaysia, 72% in Ethiopia and 53.3% in Nigeria.¹⁰⁹

In truth, it is estimated that over 600 million hours are lost from work each year due to dysmenorrhoea.¹¹⁰ With an average loss of two or more working days per female employee per month and dysmenorrhoea has become a large and costly illness.¹¹¹

Moreover, dysmenorrhic girls have lower school marks and more school adjustment problems than do nondysmenorrhic ones counterpart.¹¹²

3.4.6 B.M.I. IN RELATION TO PRIMARY DYSMENORRHEA:

3.4.6.1 BODY MASS INDEX:

Hirata et al. 2002 who found the frequency of dysmenorrhoea to be greatest in the underweight group. This study established a positive relationship between dysmenorrhoea in adolescents and low BMI reflecting their poor dietary intake.¹¹³

Madhubala Chauhan et al 2012 conducted a Cross-sectional study of 200 urban and 200 rural school going adolescent girls at Udaipur and Bedla Districts, Rajasthan. The results showed that there is a relation between dysmenorrhoea and BMI was found to be significant ($p < 0.01$) with **increased prevalence in the low BMI group**. Hence, improving the nutritional status of adolescent girls may help in reducing dysmenorrhoea.

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Hong Ju et al did a study that aims to investigate the long-term association between BMI and dysmenorrhea. 9,688 women from a prospective population-based cohort study were followed for 13 years. The Data were collected through self-reported questionnaires. The result showed a longitudinal association between dysmenorrhoea and BMI. The study revealed a U-shaped relationship between BMI and dysmenorrhoea, with both underweight and obese are significantly associated with the dysmenorrhoea.

Maintaining a healthy weight is important for women to have pain-free periods. It found that BMI < 20 kg/m² was connected with dysmenorrhoea and no relationship was demonstrated between BMI > 24 kg/m² and dysmenorrhea.¹¹⁵

Table 1: The International classification of adult underweight, overweight and obesity according to BMI¹¹⁶

Classification	BMI (Kg/m ²)	
	Principal cut-off points	Additional cut-off points
Underweight	<18.50	<18.50
Severe thinness	<16.00	<16.00
Moderate thinness	16.00 – 16.99	16.00 – 16.99
Mild thinness	17.00 – 18.49	17.00 – 18.49
Normal range	18.50 – 24.99	18.50 – 22.99
		23.00 – 24.99
Overweight	>= 25.00	>= 25.00
Pre-obese	25.00 – 29.99	25.00 – 27.49
		27.50 – 29.99
Obese	>= 30.00	>= 30.00
Obese class I	30.00 – 34.99	30.00 – 32.49
		32.50 – 34.99
Obese class II	35.00 – 39.99	35.00 – 37.49
		37.50 – 39.99
Obese class III	>= 40.00	>= 40.00

3.4.7 MANAGEMENT FOR PRIMARY DYSMENORRHOEA:

1. Conventional system of management (Pharmacological therapy)

- a. Non-steroidal anti-inflammatory drugs (NSAIDs)
- b. COX-2 inhibitors
- c. Transdermal glyceryl trinitrate
- d. Oral contraceptives
- e. Progestin regimens
- f. Levonorgestrel Intrauterine System
- g. Calcium channel blockers
- h. Simple analgesics

2. Surgical interventions

- a. Hysterectomy
- b. Laparoscopic uterine nerve ablation
- c. Presacral neurectomy

3. Complementary and alternative medicine:

- a. Nutritional Supplements

b. Herbal Remedies:

c. Transcutaneous Electrical Nerve Stimulation(TENS)

d. Acupuncture

e. Acupressure

f. Exercise

g. Magneto therapy

h. Massage

i. Behavioral intervention

3.4.7.1. Conventional system of management (Pharmacological therapy)

a. Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are analgesics which is the standard medical management for dysmenorrhoea and it inhibit the cyclooxygenase (COX) enzymes, thereby inhibiting the production of prostaglandins. Pharmacological intervention with common used drugs aspirin, Diclofenac, ibuprofen, ketoprofen, meclofenamate, mefenamic acid, and naproxen acetaminophen have been providing symptomatic relief. Nonsteroidal anti-inflammatory drugs (NSAIDs) are the best-established initial therapy for dysmenorrhea.¹¹⁷ However, these drugs are not 100% effective and are related with side effects.

b)COX-2 inhibitors

Prostaglandin synthesis which is mediated primarily by 2 different isoforms of cyclooxygenase (COX-1 and COX-2), which catalyze the metabolism of arachidonate to prostaglandin H₂. The Conventional NSAIDs are non-selective inhibitors of both isoforms of COX. It has been proposed that the therapeutic efficiency of NSAIDs is primarily the result of cyclooxygenase-2 (COX-2) inhibition, whereas their well-recognized gastrointestinal toxicity and disruption of platelet function is derived from inhibition of cyclooxygenase-1 (COX-1) activity.¹¹⁸

In a double-blind study¹¹⁸ comparing meloxicam 7.5 mg and 15 mg once a day with mefenamic acid 500 mg three times a day, both of the daily doses of meloxicam were comparable to mefenamic acid t.i.d. in relieving dysmenorrhea symptoms, and meloxicam had a better gastrointestinal tolerability profile. Both rofecoxib (Vioxx) and valdecoxib (Bextra) have been withdrawn from the market because of cardiovascular concerns (rofecoxib, valdecoxib) and potentially lifethreatening skin reactions (valdecoxib).

c. Transdermal glyceryl trinitrate

Transdermal glyceryl trinitrate has a relaxing effect on the myometrium. In a study comparing glyceryl trinitrate with diclofenac,¹¹⁹ both the treatments significantly reduced the pain intensity score by 30

minutes. Though, diclofenac continued to be effective in reducing pelvic pain for 2 hours while glyceryl trinitrate did not. Headache was significantly increased by glyceryl trinitrate. This study indicates that glyceryl trinitrate has a reduced efficiency and tolerability by comparison with diclofenac in the treatment of primary dysmenorrhea. When the glyceryl trinitrate patch was compared with a placebo patch, the pain intensity differences from 1 to 6 hours were statistically significant in favour of active treatment. The incidence of the headache was 26% for the active drug and 6.1% for placebo.¹²⁰

d.Oral Contraceptives

Oral contraceptive pills (OCP) are used as a second-line treatment. OCP prevent ovulation and improve dysmenorrhoea by reducing the amount of endometrial tissue available for PG and leukotrienes. One potential disadvantage of the use of OCPs is the possible adverse effects that can accompany the two hormones used. Oestrogen associated side effects may include nausea, vomiting, headaches, breast tenderness, and changes in body weight; progestogenic side effects may include acne, weight gain, increased hair growth, and depression.¹²¹

e. Progestin regimens

The Depot medroxyprogesterone acetate (DMPA) works primarily by suppressing the ovulation.¹²² It can also induce endometrial atrophy.¹²³ One of its non-contraceptive benefits is amenorrhea with a resultant reduction in the incidence of dysmenorrhoea. Amenorrhea rates are 55% to 60% at 12 months and 68% at 24 months.¹²⁴ For this reason, the DMPA may be considered in the treatment of dysmenorrhea.¹²⁵⁻¹²⁷ The progestin only pill (POP) may decrease menstrual flow, and up to 10% of POP users will build up amenorrhea. Menstrual cramping may be decreased; however, no studies have been done to date.

f. Levonorgestrel Intrauterine System

It is Commonly used for heavy menstrual bleeding, the hormonal intrauterine system can help to relieve pain by reducing heavy blood flow.¹²⁸ The Side effects include irregular menstruation.e.g. in nulliparous women.

g. Calcium channel blockers

Calcium antagonists can reduce myometrial activity and alleviate dysmenorrhoea by controlling the cytoplasmic concentration of free calcium and thereby the contractions of the uterine muscle.¹²⁹

h.Simple analgesics

Simple analgesics, such as aspirin and paracetamol are useful as a starting point especially when NSAIDs are contraindicated.^{117,130}

3.4.7.2Surgical interventions

a) Hysterectomy

The Pelvic pain should be carefully investigated prior to considering a hysterectomy. There is a case for hysterectomy when an underlying disease, amenable to hysterectomy, is demonstrated and the patient has completed her family. Hysterectomy may offer permanent relief for the woman who has pain restrained to her menses, and therefore there is good evidence for excellent patient satisfaction following hysterectomy.¹³¹⁻¹³⁴

b)Presacral Neurectomy

Presacral neurectomy (PSN) involves the total transaction of the presacral nerves lying within the boundaries of the interiliac triangle. PSN seems to be the method of pelvic denervation that is linked with the major long-term effectiveness in pain relief^{135,136} Some of the complications of this procedure may include constipation as well as urinary urgency which is unlikely to respond to medical treatment. This side effect was observed in 5% of women treated with PSN.¹³⁷

c)Laparoscopic Uterosacral Nerve Ablation (LUNA)

The Resection of the uterosacral ligaments achieves more complete uterine denervation than presacral neurectomy. The intervention carry the risk for complications such as bleeding, ureteral lesions, and pelvic support disorders.¹³⁸ In one study involving 180 women scheduled to undergone laparoscopy for pain and endometriosis, 78 women had uterosacral ligament resection. One year later, 29% of women in this group had persistent dysmenorrhoea. Of the 78 women who had conservative surgery only, 27% had recurrent dysmenorrhoea. Addition of uterosacral ligament resection did not diminish dysmenorrhea.¹³⁹

Surgical therapies, an Observational data showed that one year after the procedure, pain relief persisted in 82% of women having presacral neurectomy and in only 51% having LUNA. Information about long term outcomes is lacking. A Cochrane meta analysis of surgical interruption of pelvic nerve pathways as a management for dysmenorrhoea concluded that evidence was insufficient to suggested the procedure, regardless of the cause of the dysmenorrhoea.

3.4.7.3 Complementary and Alternative Medicine:

a) Nutritional Supplements:

Thiamine (100mg-daily), Vitamin E-2500 IU-5 days, omega-3 polyunsaturated fatty acids-2g daily, fish oil supplement all these supplement helps to relieve dysmenorrhoea.

Interventions included 12 different herbal medicines (German chamomile (*Matricaria chamomilla*, *M recutita*, *Chamomilla recutita*), cinnamon (*Cinnamomum zeylanicum*, *C. verum*), Damask rose (*Rosa damascena*), dill (*Anethum graveolens*), fennel (*Foeniculum vulgare*), fenugreek (*Trigonella foenum-graecum*), ginger (*Zingiber officinale*), guava (*Psidium guajava*), rhubarb (*Rheum emodi*), uzara (*Xysmalobium undulatum*), valerian (*Valeriana officinalis*), and zataria (*Zataria multiflora*)) and five non-herbal supplements (fish oil, melatonin, vitamins B1 and E, and zinc sulphate) in a variety of formulations and doses. Comparators included other supplements, placebo, no treatment, and NSAIDs.¹³¹ For treating primary dysmenorrhoea, there was no evidence of effectiveness for vitamin E, and no constant evidence of effectiveness for dill, guava, or fennel. There was very limited evidence of effectiveness for fenugreek, fish oil, fish oil plus vitamin B1, ginger, valerian, vitamin B1 alone, zataria, and zinc sulphate.¹⁴⁰

Some studies have shown that zinc may prevent or improve primary dysmenorrhea. There are several hypotheses on how zinc does this, for example, by promoting microcirculation and preventing ischemia, and inactivating oxygen free radicals. Zinc can also downregulate and reduce inflammatory cytokines and regulate the levels of COX-1 and COX-2 as well as inhibit the metabolism of PG, similar to NSAIDs.¹⁴¹⁻¹⁴⁷

b)HERBAL REMEDIES:

FENNEL:

Ziaei et al said that in his study that fennel is an effective, safe, and suitable remedy for reducing dysmenorrhoea.*Foeniculum vulgare* contains an antispasmodic and anethol agents.¹⁴⁸ For centuries, fennel fruits (*F. vulgare*) have been used as traditional herbal medicine in Europe and China.¹⁴⁹ Fennel seeds were one of the acceptable herbal drugs of primary dysmenorrhea in Iran.^{150,151}

c)TOKI-SHAKUYAKU-SAN (TSS)

The Japanese herbal remedy toki-shakuyaku-san (TSS) has been shown in an RCT to be better than placebo in the treatment of women with dysmenorrhoea. There are insufficient data to evaluate other herbal products

.¹¹⁷

d)TOPICAL HEAT

Akin et al conducted a randomized placebo-controlled trial in that they compared the effectiveness of topically applied heat for dysmenorrhoea with the use of oral ibuprofen and placebo treatments Low-level topical heat therapy was effective for the treatment of dysmenorrhoea. In addition, there was a faster improvement in pain relief when heat was applied with ibuprofen compared with the ibuprofen and unheated patch control.¹⁵²

e)TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION(TENS)

TENS has been studied that it will reduce primary dysmenorrhea. The investigators found that high-frequency TENS considerably reduces the pain of primary dysmenorrhoea and the amount of pain medication required.¹⁵³

TENS appears to be a appropriate method of relieving primary dysmenorrhoea in women who may not wish to take medication, have medical contraindications to the use of nonsteroidal antiinflammatory drugs or birth control pills, have adverse effects from the use of nonsteroidal anti-inflammatory drugs, or are unable to obtain total relief with maximum doses of non steroidal anti-inflammatory drugs.

TENS relieves primary dysmenorrhea through two likely mechanisms. First, with continuing transcutaneous electrical nerve

stimulation, the preganglionic fibers are bombarded with impulses, which saturate the nerve cells of the dorsal horn and as a result block the transmission of pain impulses along these fibers (gate control theory). Second, TENS induces release of endorphin from these nerve cells that contributes to the relief of pain.¹⁵³

In dysmenorrhoea, TENS seems to work by alteration of the body's ability to receive or perceive pain signals rather than by having a direct effect on the uterine contractions .¹⁵⁴

f) ACUPUNCTURE

Women received nine sessions of the study treatment over 3 months. The primary outcomes were menstrual pain intensity and duration, overall improvement in dysmenorrhoea symptoms and reduced need for additional analgesia, measured at 3, 6 and 12 months from trial entry. At 3 months Women receiving acupuncture reported a small reduction in mood changes compared with the control group. Follow-up at 6 months found a significant reduction in the duration of menstrual pain in the acupuncture group compared with the control group.¹⁵⁵

A Study done to evaluate the effect of acupuncture on NSAID resistant dysmenorrhoea related pain in 15 consecutive patients. Pain was measured at baseline (T1), mid treatment (T2), end of treatment (T3) and 3 (T4) and 6 months (T5) after the end of treatment. Substantial reduction of

pain and NSAID assumption was observed in 87% patients. Findings of this study suggest that acupuncture may be indicated to treat dysmenorrhea related pain, in particular in those subjects in whom NSAID or oral contraceptives are contraindicated or refused.¹⁵⁶

Across over clinical trial showed that Acupressure at the SP6 and SP8 points can reduce pain severity of dysmenorrhea for up to 2 hours after application, and these points may be used to alleviate the severity of systemic symptoms accompanying dysmenorrhea.¹⁵⁷

A clinical study conducted dry cupping for dysmenorrhea on 27 patients with the age group 12-37, 2 glass cup of medium sized were applied below the umbilicus for 15 minutes on day 1 and 2 of menstrual cycle and the pain intensity was assessed by visual analogue scale and before and after treatment and the results were shown effective in reducing pain intensity in dysmenorrhea.¹⁵⁸

A study was conducted with the purpose of comparing the effectiveness of acupressure, fish oil capsules, and ibuprofen in treating primary dysmenorrhea. Students afflicted with primary dysmenorrhea were randomly divided into three groups. The first group received 1000 mg of fish oil capsule every day for the duration of two successive cycles; the second group was given 400 mg ibuprofen pills, as soon as the pain started, for two months; and in the acupressure group the Sanyinjiao point was pressed, at the start of the pain, with a thumb for 20 min. Results showed

that there was a significant difference with respect to pain before and after the use of the medicines and acupressure ($P = 0.000$).¹⁵⁹

h) EXERCISE

The first medical report claiming that exercise might help to relieve dysmenorrhoea was by Billing in 1943. It is proposed that women with dysmenorrhoea had contracted ligamentous bands in the abdomen and he therefore developed a series of stretching exercises for which he claimed a high rate of symptomatic relief.¹⁶⁰

Izzo and Labriola showed that dysmenorrhea was less prevalent in athletes who had begun their sports activities prior to menarche, and that there was improvement in symptoms after initiation of exercise, and athletes participating in more intense sports activities had less severe menstrual symptoms.¹⁶¹

A clinical study conducted on Effects of Aerobic Training on Primary Dysmenorrhoea Symptomatology in 36 College Females, 18 in each control and intervention group. Control subjects remained sedentary throughout and the experimental period while the training group participated in a 30-minute continuous walking or jogging program 3 days per week for 12 weeks. The study revealed that aerobic training can significantly reduce menstrual cycle symptoms linked with primary dysmenorrhoea.¹⁶²

A study on 40 women with primary dysmenorrhoea aimed to examine the impact of home-based exercise on pain intensity and quality of life in women. A home-based exercise programme (lasting for 12 weeks, 3 times a week) was suggested for the patients. They were followed up for 3 menstrual cycles and each month the VAS and SF-36 scores were recorded. Pain intensity was measured on the visual analogue scale (VAS), and health-related quality of life (HRQoL) was assessed with the SF-36 health survey. In this study, home-based exercise intervention given a significant improvement in HRQoL and a reduction of pain in patients with primary dysmenorrhoea.¹⁶³

A randomized clinical trial of 150 students suffering from severe dysmenorrhoea was studied in two exercise and non exercise groups. The intensity of the pain in the exercise group dropped from 8.59 to 4.63 in the third period and 2.84 in the fourth period. The average of pain duration declined from 7.15 hours to 4.22 hours in the third period and 2.23 in the fourth period, and the difference of $p < 0.01$ is seen in the groups. The average of using sedative tablets also decreased from 1.13 tablets to 0.35 tablets in the third period and 0.0 tablets in the fourth period, which the difference is $p < 0.01$ between the two groups.¹⁶⁴

i) SPINAL MANIPULATION

A review of 44 dysmenorrheic women found that High-velocity low-amplitude spinal manipulation drastically reduced pain intensity, as measured by a 10 cm visual analogue scale pain score after one treatment and one menstrual cycle, compared with placebo manipulation identified by the review compared 3 months of spinal manipulation versus placebo manipulation. This study significantly reduced pain intensity after 6 months compared with placebo.¹⁶⁵

j) MAGNETO THERAPY

An randomized control trial of a static magnet 0.27 attached over the pelvic area compared with a placebo in women with primary dysmenorrhoea. This study showed a considerable reduction in pain and other systemic symptoms. A larger placebo controlled study found significant relief of primary dysmenorrhoea pain with magnet (2500 gauss) compared with the placebo magnet.¹⁶⁶

k) MASSAGE

A Preliminary Controlled Clinical Study conducted on Aromatherapy, Massage on the Abdomen for Alleviating Menstrual Pain in High School Girls. Massage was given to the abdomen once using clary sage, marjoram, cinnamon, ginger, and geranium in a base of almond oil. The level of menstrual pain was assessed using a VAS at baseline and

twenty-four hours afterward. The reduction of menstrual pain was significantly higher in the aromatherapy group than in the acetaminophen group.¹⁶⁷

D)BEHAVIORAL INTERVENTION AND LIFESTYLE

MODIFICATION:

Denny et al done a review study on Behavioural interventions for the treatment for dysmenorrhoea was effective in treating dysmenorrhea. It includes various procedures such as biofeedback, desensitization, Lamaze exercise, hypnotherapy, and relaxation training.¹⁶⁸

Few studies have examined that the effect of lifestyle modification interventions in the management of dysmenorrhoea. One cross –over study of a low –fat vegetarian diet versus placebo pill showed decreased duration and intensity of dysmenorrhoea in women in the intervention group. Even though some studies have reported a benefit with exercise ,the effect is questionable because participants were not blinded to the study hypothesis.Smoking cessation has not been studied as an intervention to manage dysmenorrhoea.¹¹⁷

m)YOGA THERAPY:

The Asanas will help in removing the congestion in internal organs, especially uterus, which is one of the reason for dysmenorrhoea pain. The practice of Pranayama helps to 24 reduce sympathetic dominance

which is considered to be one of the causative factors for dysmenorrhoea pain. Moreover the practice of Yoga helps in establishing a balance between the endocrine & reproductive systems and regulates the hormonal control of the menstrual cycle.¹⁶⁹

A study conducted by Usha Nag et al conducted a study on the effect of Yoga on primary dysmenorrhoea and Stress in Medical students, it was shown that Yoga gave a significant reduction in pain and perceived Stress. The study was conducted in 113 medical students, with primary dysmenorrhoea and stress. They were assigned to study and control group and Semi structured questionnaire, the Numerical rating scale for pain and the Perceived Stress Scale (PSS) were given during baseline and after the study period of three months. After three months of yoga intervention 49 subjects (82%) reported complete stress relief, 8 subjects reported average stress and 3 reported slightly higher than average stress. There was significant ($p < 0.0001$) enhancement in the stress levels after three months of yoga intervention.¹⁷⁰

It was observed that after yoga intervention there was a significant ($p < 0.0001$) reduction in the perceived pain using Friedman test. 88% of subjects from the study group reported complete pain relief and 12% of subjects reported mild pain. In difference, there was no reduction of pain in control group.¹⁷ The results proposed that psychosocial stress is independently related with menstrual pain and that Yoga has found to be an

effective alternative treatment to produce pain relief in primary dysmenorrhoea. The study also suggested that alternative Measures like yoga reduces psychosocial stress levels and must be implemented among college students to augment menstrual well-being. This may also helpful in preventing future illness from happening.¹⁷⁰

In another study conducted by Zahra Rakhshae et al in 2011 on the effect of three Yoga Poses (Cobra, Cat and Fish poses) in women with Primary Dysmenorrhea, It was observed that the mean of pain duration before doing yoga were 37.49 in experimental group and 40.57 in control group. After the practice of yoga for 20 minutes for duration of 3 months, the duration of pain in the experimental group was 32.1 and control group was 40.0. This shows there is a significant reduction ($P=0.000$) in both the duration and intensity of pain in experimental group after the practice of yoga.¹⁷¹

n) ROLE OF NATUROPATHY:

The Naturopathic procedures act by improving blood circulation to the reproductive organs and by relieving congestion in the pelvic region. The treatment used for Dysmenorrhoea includes Revulsive compress over the pelvic region, Neutral Hip Bath, Revulsive Hip Bath, Mud pack to abdomen, Abdominal pack etc. depending upon the type of Dysmenorrhoea.³²

For Dysmenorrhoea Hot fomentations-lower abdomen and lower back ,Hot Hip bath,hot foot bath etc have been indicated with such profound benefits of cold application ,but there were no studies with cold application especially cold hip bath this make to to do this study.

3.4.8EFFECT OF HYDROTHERAPY ON HUMAN BODY:

Hydrotherapy is a branch of naturopathic medicine that involves the use of water at different temperatures ,pressures ,duration and modes of application.It is also known as water therapy.¹⁷²

The physiological effects of hydrotherapy may be classified as thermal, mechanical ,chemical. Thermal effects are produced by the application of water at temperature below or above body temperature.

The greater the variation from body temperature ,the greater the effect produced .

Mechanical effects are produced by the impact of water acting on the body surface in the form of sprays, douches, friction , immersion etc.

Chemical effect are produced when water is taken by mouth or used to irrigate a body cavity, such as the large colon.

Thermal effects are used commonly for therapeutic purpose. In general hot relaxes and sedates, while cold stimulates ,invigorates and tonifies.

The application of water at different temperatures one can increase or decrease the rate of blood flow through an organ or area of the body and can either increase or decrease the total volume of blood in an organ or area of the body based on the physiological principles revulsive effect ,derivative effect , Spinal cord reflex, collateral circulation and arterial trunk reflex.¹⁷³

Cold application initially causes skin vasoconstriction and if a cold compress covers a large of the body , a significant amount of blood will be driven into the internal organs. Prolonged cold causes a secondary reaction , inducing vasodilatation of the surface skin blood vessels.The time required to qualify as prolonged cold will vary , dependent upon method of application.¹⁷⁴

3.4.8.1 COLD HIP BATH :

The hip bath or sitz bath is one of the oldest and most useful hydrotherapeutic procedures.³¹



Figure 5: cold hip bath tub

PROCEDURE:

- The hip bath tub may be of metal, porcelain, or wood. It should be of such form and size that the patient may be comfortably seated in it by leaving the feet outside.³¹
- The limbs should be flexed and the feet placed in a foot rest. The temperature of water employed in the cold hip bath should be 55° F to 65° F. The duration of the therapy should be 1 to 8 minutes.³¹
- The tub is filled with adequate water to cover the lower abdomen, hips and upper two thirds of thighs so that the water reaches the level of the navel.³¹
- The patient should be rubbed sufficiently to prevent chills. Care should be taken to keep the feet warm. The limbs should be adjusted so that there will be no pressure upon the popliteal fossa, as this will interrupt the circulation in the feet and with the results of the bath.³¹



Figure 6: Cold hip bath

3.4.8.2 PHYSIOLOGICAL EFFECTS OF COLD HIP BATH:

Dr.J.H.Kellogg states that A short application (50° – 70 °F), duration 5- 8 minutes produce tonic effects. when the cold application is a short one,then the reaction follows quickly, and is as much more powerful as the application made is energetic. Cold is a vital depressant. When the cold application is made to the body in any form the first effect is a

lessening of the tissue activity. If the application is a short one then the reaction follows immediately by increasing the tissue activity and increase the tonic reaction.³¹

The Short cold sitz produces active dilatation of the vessels of the lower abdomen. The thermic reaction produced, heightens the nutritive processes in the parts concerned, and excites contraction of the muscular structures of the viscera, thus influencing the pelvic organs, together with the various musculo-ligamentous structures which will support the pelvic viscera.³¹

The prolonged cold sitz (15 to 20 minutes) causes very pronounced effects upon the pelvic circulation. The contraction of the cutaneous branches of the internal iliac tends to produce the hyperemia of the pelvic viscera.³¹

3.4.8.3 TONIC EFFECTS:

The tonic effects of cold water gives the good constant and regular effect being exerted whenever the water is applied at a temperature below that of the body.

Trousseau defined tonic as a agent which will tone the tissues, to restore the nutrition and assimilation functions and to increase the vital resistance. It promotes the renewal of the body.³¹

The best tonic effect will obtain by the repetition of excitant measures i.e short cold application. The reaction produced by tonic applications fills the skin with blood ;and if it is repeated daily, then the blood flow to the skin is increased and thereby increasing the vascular activity and thus relieving the internal congestion.

All applications of water with a temperature below 90° F are tonic and increase the vital resistance.³¹

If the application which are tonic when we give off in shorter duration, become sedative when sufficiently prolonged. The best effect will be obtained by very cold and very short baths.³¹

3.4.8.4 REFLEX EFFECTS :

When the application is general, the mechanical effect is dominant; when it is given to local area then reflex effect is dominant.

When we give treatment to the lumbar region, lower abdomen the breast, the inner surface of the thighs, the feet ,cervix and the vagina will act on uterus.

The reflex areas for uterus are the lumbar region, the abdomen, the breast, the inner surface of the thighs, the feet and to the cervix uteri, through the vagina.

A Very cold applications to the breast, abdomen, hands and feet cause contraction of the involuntary muscles of the bladder, bowels and uterus. It is more possible that the muscular structures of the liver, spleen and other viscera are likewise influenced by the applications made to the overlying areas of skin.³¹

3.4.8.5 COLD HIP BATH INDICATED FOR PRIMARY DYSMENORRHOEA IN VARIOUS BOOKS :

Dr. H. K. Bakhru states that Dysmenorrhoea can be relieved by proper attention to diet and hot hip baths just before the period is due and cold hip baths between the periods. Between periods, cold hip baths will increase the tone of the ovaries. The cold hip bath should be taken for 10 to 15 minutes at a water temperature of 50° to 65°F.¹⁷⁵

Dr. Ravindra V. Nisal, Dr. Hema R. Arya et al states that dysmenorrhoea can be managed by cold hip bath.¹⁷⁶

Dr. VithaldasModi states that dysmenorrhoea can be managed by taking cold hip bath at a temperature of 10 to 15°F lower than body temperature¹⁷⁷.

Dr. Nil KantaChakraborty states that dysmenorrhoea can be managed by taking cold hip bath for eight minutes for two weeks before menstruation.¹⁷⁸

4.0 MATERIALS AND METHODOLOGY:

4.1 STUDY DESIGN:

A Randomized control trial

4.2 SUBJECTS:

A total of 85 female subjects were selected to participate in the study based upon the symptoms experienced. All subjects were subjected to pelvic scan to rule out any pathologies. Out of 85 subjects 17 had PCOs and were therefore excluded from the study.

The remaining subjects were briefed about the study and informed consent was obtained from them along with permission from their parents in case of minor. This study was conducted within the purview of a larger study on the physiological effects of cold hip bath, and ethical approval was obtained from institutional ethics committee for the entire study.

After getting informed consent from the patient Menstrual symptom questionnaire(MSQ), Visual analogue Scale (VAS) and will be given for all participants to score dysmenorrhoea-related symptoms. The cold hip bath treatment duration 8 minutes at 55 -65 ° F will be given from the sixth day of menstrual period to the next menstrual cycle. After intervention (MSQ) and (VAS) will be given for all participants .

They were asked to fill the menstrual symptom questionnaires” and were also asked to mark the intensity of pain in Visual Analogue scale (VAS) at the beginning of the study. Their detailed history was also collected. Out of the remaining 68 subjects 8 subjects discontinued with the practice during different time of the study. All subjects are free to withdraw from participation in the study at any time, for any reason, specified or unspecified, and without prejudice to further treatment. Subjects who are withdrawn from the study were not being replaced.

The subjects were selected based on the following criteria:

4.2.1 Subject Selection:

4.2.1.1 Inclusion Criteria:

- Subjects must be between 16 to 25 years of age.
- Dysmenorrhoea in majority of menstrual cycles.
- Women with regular menstrual cycles.
- Suffering from dysmenorrhoea at least since a year.
- Those who are willing to participate in the study by signing an informed consent.

4.2.1.2 Exclusion Criteria:

- Participants will be excluded with pelvic pathology(secondary dysmenorrhoea).
- Suffering from any systemic illness
- Subjects whose BMI are at and above 28 are excluded
- Menorrhagia will be excluded

4.3 INTERVENTION:

Cold hip bath was given to the subjects. Cold hip bath is given regularly for one month. Pain intensity was measured at the beginning of each cycle.

Subjects were asked to visit hospital daily for the treatment from sixth day of last menstrual cycle to the next cycle.

Study was conducted from the sixth day of menstrual cycle to the next menstrual cycle. After the menstrual cycle, the subjects were assessed for the intensity of pain and the intensity of symptoms with the help of VAS scale and modified menstrual symptom questionnaire.

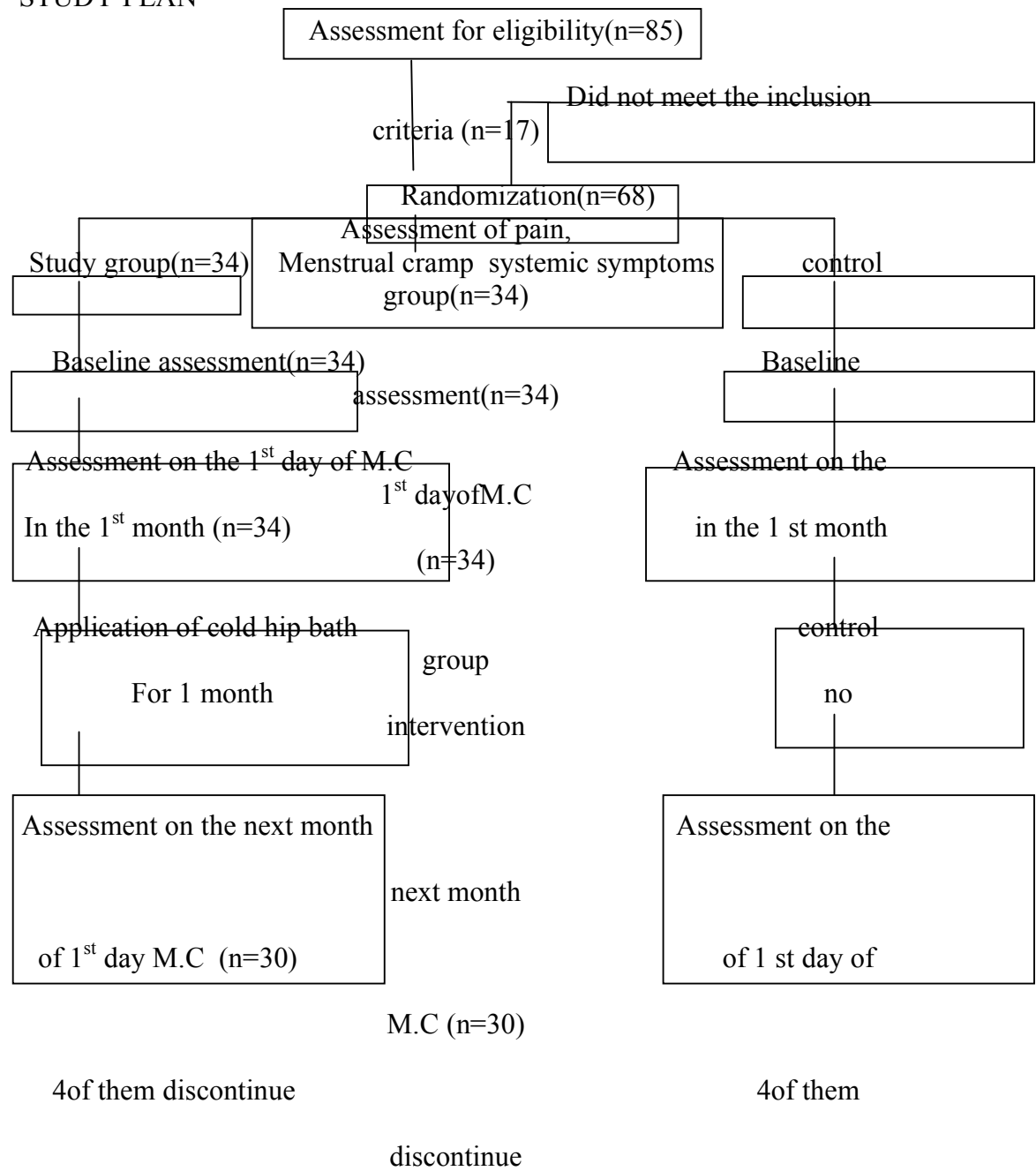
PROCEDURE:

- The hip bath tub may be of metal, porcelain, or wood. The hip bath tub measures about (406 mm*609 mm *609 mm). It should be of such

form and size that the patient may be comfortably seated in it by leaving the feet outside.³¹

- The patient should be in empty stomach.
- The limbs should be flexed and the feet placed in a foot rest. The temperature of water employed in the cold hip bath should be 55° F to 65° F. The duration of the therapy should be 1 to 8 minutes.³¹
- The tub is filled with adequate water to cover the lower abdomen, hips and upper two thirds of thighs so that the water reaches the level of the navel.³¹
- The patient should be rubbed sufficiently to prevent chills. Care should be taken to keep the feet warm.³¹

STUDY PLAN



4.4 ASSESSMENT:

The assessment tools used in the study are Modified Menstrual Symptoms Questionnaire and visual analogue scale. Dysmenorrhoea-related symptoms were scored using Modified Menstrual Symptoms Questionnaire. V.A.S. scale was used to assess pain at the beginning of menstrual cycle to next menstrual cycle.



Figure 8:Assessment

4.4.1 MENSTRUAL SYMPTOM QUESTIONNAIRE:

Menstrual Symptom Questionnaire (MSQ) which includes 24 items that are rated as 1 = “never” to 5 = “always”. Previous research has found support for 2 factor and 5 factor solutions of the items. The 2 factors each have 12 items which are summed to provide a score on Spasmodic and Congestive dysmenorrhoea. Items in the Spasmodic factor generally reflect symptoms occurring during menstruation like spasms similar to labor pains while items in the Congestive Factor generally reflect symptoms or moods in the premenstrual phase. The (possible) range of scores was 12–52 for both the Spasmodic factor and the Congestive factor.¹⁹

4.4.2 VISUAL ANALOGUE SCALE:

The Visual analogue scale developed by Cline.¹⁷⁹ The Visual analogue scale (VAS) provides a continuous scale for subjective magnitude estimation and consists of a straight line, the limits of which carry a verbal description of each extreme of the symptom to be evaluated. The line is usually 10 cm long and horizontal,¹⁸⁰ though different lengths and orientations have been employed and proven satisfactory.^{181,182} The VAS using a 10-cm line represented the continuum of the female student's opinion of the degree of pain before and after intervention. One extremity of the line represented “unbearable pain,” and the other extremity represented “no pain

at all.” The participants were asked to rate the degree of pain by making a mark on the line. The scores received from the scale were classified into mild dysmenorrhoea if it was between 1 and 3 points moderate between 4 and 7 points, and severe between 8 and 10 points.¹⁸³ The visual analog scale (VAS) is a tool widely used to measure pain. Subjects were asked to indicate a perception of pain intensity along a 10 cm horizontal line.



Figure 9: visual analogue scale

Statistical Analysis:

Data expressed Mean \pm SD. Comparison of Mean in between the group was analyzed by paired t test and unpaired t test which is applicable. R statistical software version 3.1.1 was used for the analysis.

5.0 RESULTS

The present study was conducted to evaluate whether cold hip bath had any influence in any of the outcome variable like in pain and menstrual related symptoms during primary dysmenorrhoea. Results were compared within and between groups, wherein data was extracted at baseline and post intervention for outcome variable.

Table: 2 Anthropometric parameters and vital datas of the study participants

Variable	Study group	Control group	P value
Age (yr)	19.8±4.6	17.8±6.6	0.23
Height (cm)	145.2±9.26	149.9±5.46	0.90
Weight (kg)	56.06±8.08	58.02±9.28	0.45
BMI (kg/m ²)	23.13±2.29	21.90±3.80	0.34
Respiratory Rate	14.26±1.90	16.90±3.45	0.66
Heart Rate (bpm)	86.2±4.29	82.46±6.90	0.90
SBP (mmHg)	124.66±7.79	128.16±9.80	0.32
DBP(mmHg)	79.0±7.66	74.0±7.23	0.45
PP (mmHg)	44.16±8.90	42.28±7.70	0.86

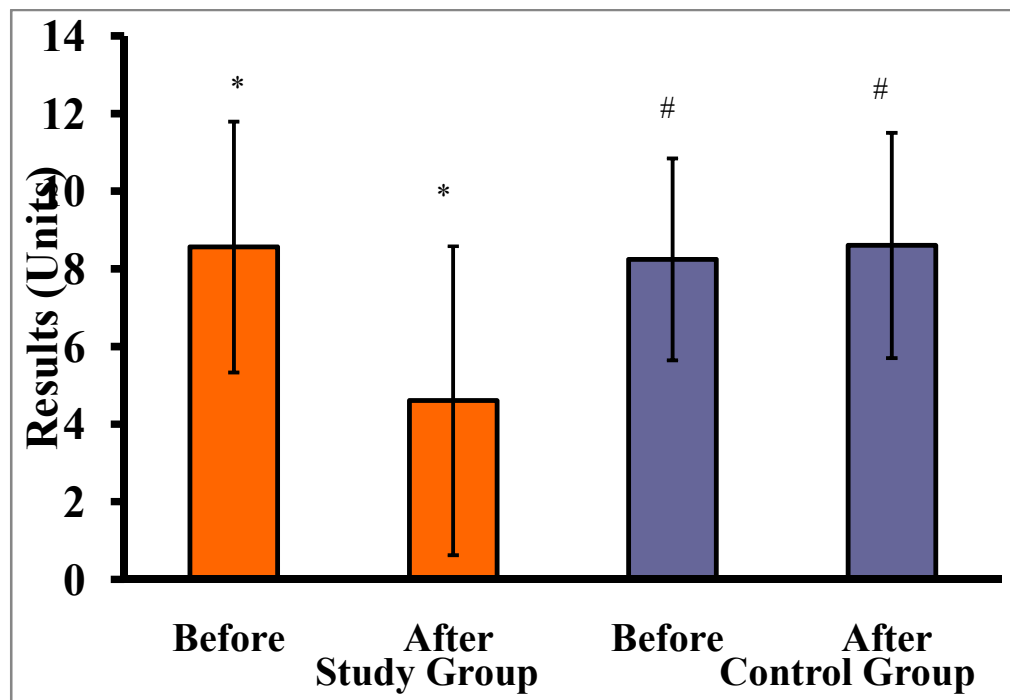
A total of 60 subjects participated and completed the intervention in the present study. Girls were in a mean age of 19.8 years, had weight (56.06 kg) and BMI (23.13 kg/m²). They had a normal range of respiratory rate (14.26 cycle/min), heart rate (86.20 beat/min), SBP (124.66 mmHg), DBP (79.0 mmHg) and PP (44.16 mmHg).

Table:3 Effects of CHB on V.A.S score in primary dysmenorrhoea

Variable	Study group		P value	Control group		P value
	Before	After		Before	After	
VAS score	8.56±3.23	4.60±3.98	0.04	8.24±2.60	8.60±2.90	0.43

After the intervention of cold hip bath(CHB) for 1 month, there was a significant (P=0.04) reduction in Visual analogue scale score in primary dysmenorrhoea. The VAS score in the first visit was 8.56±3.23 and it shows they had a discomfort during their menstrual period. After the cold hip bath intervention VAS score was significantly decreased upto 4.60±3.98.

Fig: 10 Comparison of VAS score in study and control group before and after intervention



* indicates significance at $p < 0.04$ # indicates significance at $p < 0.43$

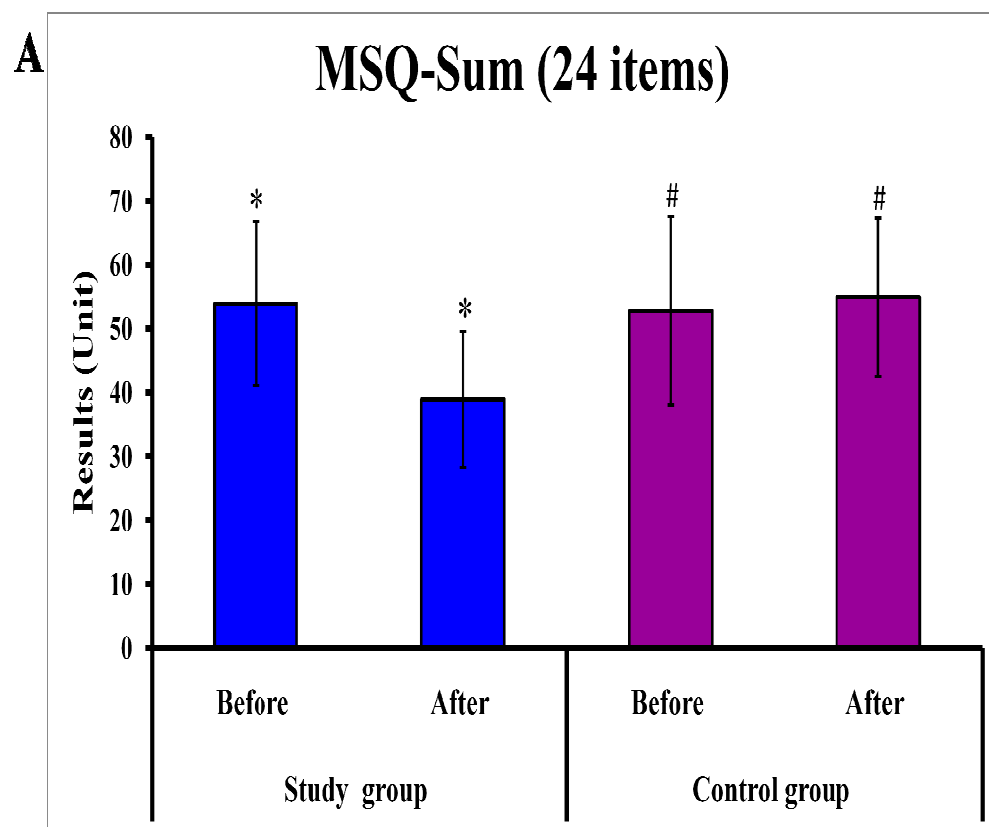
Variable	Study group		P value	Control group		P value
	Before	After		Before	After	
MSQ- Sum (24 items)	53.90±12.88	38.88±10.65	0.01	52.82±14.78	54.88±12.42	0.43
MSQ – C (12 items)	24.56±3.40	19.78±3.89	0.02	26.78±4.67	24.87±4.50	0.34
MSQ – S (12 items)	27.80±4.60	23.87±7.10	0.04	25.82±4.90	27.27±6.87	0.24

Table:4 -Effect of CHB on MSQ scale in primary dysmenorrhoea

MSQ overall score at baseline (53.90±12.88) was higher and reflecting that they had a painful menstruation. After the cold hip bath intervention, the overall score was significantly (P=0.01) decreased up to (38.88±10.65) and this shows the effect of cold hip bath in primary dysmenorrhoea. Same kind

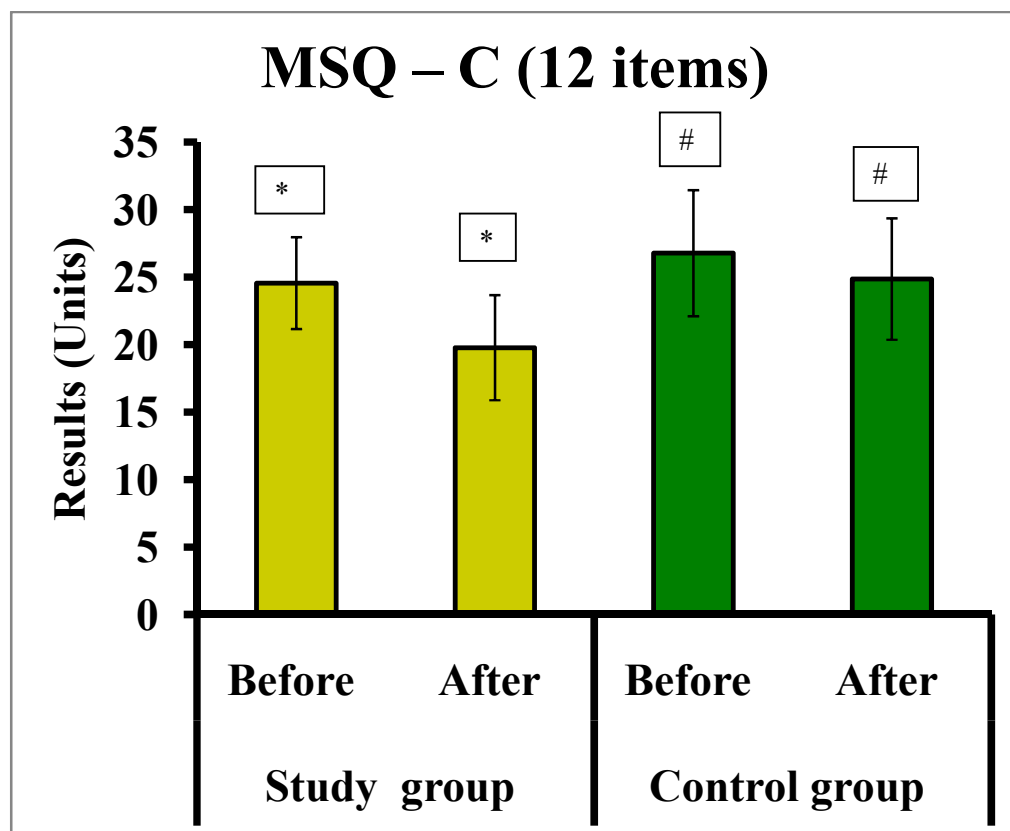
of response were obtained in the MSQ congestive factor and spasmodic factor scale and showed a significant ($P < 0.05$) reduction.

Fig:11 Comparison of MSQ score in study and control group before and after intervention



* indicates significance at $p < 0.01$ # indicates significance at $p < 0.43$

Fig:12 Comparison of MSQ score-congestive type in study and control group before and after intervention



* indicates significance at $p < 0.02$ # indicates significance at $p < 0.34$

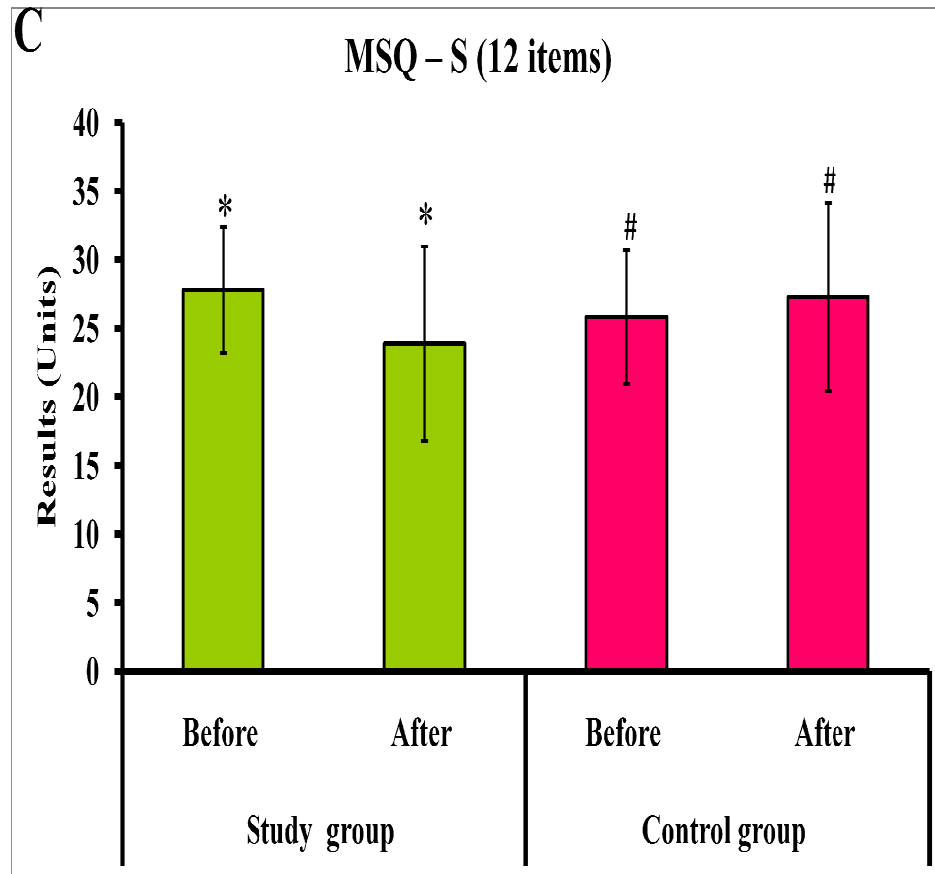
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Fig:13 Comparison of MSQ score-Spasmodic type in study and control group before and after interventio



* indicates significance at $p < 0.04$ # indicates significance at $p < 0.24$

Table 5: comparison of variable between study and control group after the intervention

VARIABLE	STUDY GROUP	CONTROL GROUP	P VALUE
VAS SCORE	4.60±3.98	8.60±2.90	0.03
MSQ-Sum (24 items)	38.88±10.65	54.88±12.42	0.01
MSQ – C (12 items)	19.78±3.89	24.87±4.50	0.01
MSQ – S (12 items)	23.87±7.10	27.27±6.87	0.04

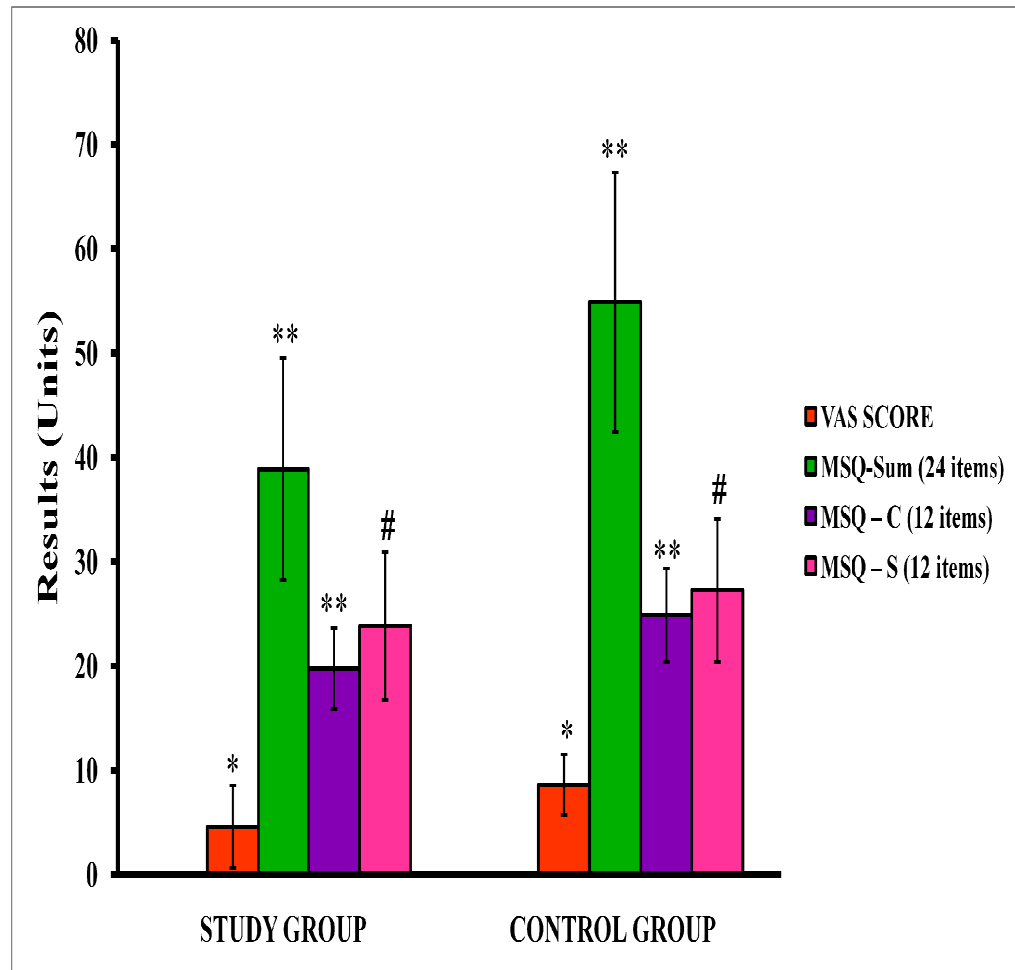


Figure 14 **comparison of variable between study and control group after the intervention**

The above table explains the results of pre and post assessment of Visual analogue scale and Menstrual symptom questionnaire among the study and

control group. The results obtained from the 30 study group subjects and 30 control group subjects.

The study group shows a significant reduction of mean while comparing to the control group and the study shows it is significant($p < 0.05$).

6.0 DISCUSSION:

This present study shows that the treatment of cold hip bath for 1 month has a positive impact on primary dysmenorrhoea as it reduces the intensity of pain and symptoms related to primary dysmenorrhoea.

V.A.S scale was used to measure the pain in primary dysmenorrhoea and it is considered to be one of the best and appropriate method to evaluate pain in primary dysmenorrhoea. During the baseline measurement, before the beginning of cold hip bath all subject had pain ranging between moderate to high intensity as marked in VAS scale. During the first visit the intensity of pain ranged from 8.56 ± 3.23 .

After the intervention of cold hip bath the VAS score was reduced up to 4.60 ± 3.98 . The reduction of mean shows that the cold hip bath has a significant effect on ($p=0.04$) reducing the pain in primary dysmenorrhoea. This shows that the cold hip bath is very much effective and has a positive effect on reducing the pain in primary dysmenorrhoea which is the objective of the study.

Pathophysiology for dysmenorrhoea is an abnormal increase in vasoactive prostanoids in endometrium and menstrual fluid. This may in turn induce myometrial hyperactivity and tissue ischemia.

Gerra G et al conducted a study in that Cold stress-induced analgesia might be mediated by increased production of opioid peptide beta-endorphin (an endogenous pain-killer).⁴³ The same mechanism may happened in this study.

Sramek P et al said in his study that Cold exposure (CE) to the small surface area produced compensatory vasodilatation in deeper vascular system resulting in increased blood flow to the tissues underlying the area of exposure. This vascular reaction occurs mainly to maintain constant deep tissue temperature.⁴⁶ The same mechanism may happened in this study.

Eric blake et al has conducted a study in that Cold application initially causes skin vasoconstriction and if a cold compress covers a large of the body, a significant amount of blood will be driven into the internal organs.¹⁷⁴

J.H .Kellogg stated that The short cold hip bath produces active dilatation of the vessels of the lower abdomen. The thermic reaction produced, will heightens the nutritive processes in the parts concerned, and excites the contraction of the muscular structures of the viscera, thus influencing the pelvic organs, together with the various musculo-ligamentous structures which will support the pelvic viscera.³¹

The best tonic effect will obtain by the repetition of excitant measures i.e short cold application. The reaction produced by tonic applications fills

the skin with blood ;and if it is repeated daily, then the blood flow to the skin is increased and thereby increasing the vascular activity and thus relieving the internal congestion.³¹

When the application is general, the mechanical effect is dominant; when it is given to local area then reflex effect is dominant.

When hydrotherapy applications to the lumbar region, lower abdomen, the breast, the inner surface of the thighs, the feet, cervix and the vagina will act on uterus.³¹

Like wise, cold hip bath will act on the reflex areas of uterus. The same mechanism may happened in this study.

It is safe and cost-effective intervention with minimal or no side effects.

MSQ is a psychometric capable of differentiating between the two types of primary dysmenorrhoea. This questionnaire supports Dalton's theory that states that hormonal imbalance as a cause of two types of primary dysmenorrhoea. It suggests that spasmodic dysmenorrhoea is caused by an excess of progesterone compared to estrogen, while congestive dysmenorrhoea is caused by an excess of estrogen compared to progesterone. This questionnaire describes the symptoms experienced by two types of dysmenorrhoea, Spasmodic and congestive. Both type of dysmenorrhoea have complete different clinical features.

The menstrual symptom questionnaire was calculated using the two factor analysis. The congestive factors of the subjects were analyzed and the mean of the baseline score was 24.56 ± 3.40 . After the intervention of cold hip bath MSQ score was reduced to 19.78 ± 3.89 which show a significant reduction ($P=0.02$) of congestive symptoms.

The spasmodic factors of the subjects were analyzed and the mean of the baseline score was 27.80 ± 4.60 . After the intervention of cold hip bath MSQ score reduced to 23.87 ± 7.10 which show a significant reduction ($P=0.04$) of spasmodic symptoms.

Since both the spasmodic and congestive factors have reduced, the overall score has also dropped down from the baseline mean from 53.90 ± 12.88 to 38.88 ± 10.65 over a period of 1 month of the intervention which shows a significant reduction ($P=0.01$) of symptoms.

The study group shows a significant reduction of mean while comparing to the control group and the study shows it is significant ($p < 0.05$).

The analysis of MSQ shows that cold hip bath not only reduces pain in dysmenorrhoea but also helps to reduce the menstrual symptoms experienced by the subjects.

According to Dalton (1969), the discomfort in spasmodic dysmenorrhoea is related to muscular tension and contractions, while the discomfort in congestive dysmenorrhoea is related to an ischemia. The blood

supply is improved to the pelvic region thus exerting a toning effect on the ovaries. It helps in the correction of both spasmodic and congestive symptoms.

7.0 CONCLUSION:

The present study suggests that cold hip bath may be effective in reducing the intensity of pain and symptoms with primary dysmenorrhoea. Cold hip bath is a simple management without any side effects.

. LIMITATIONS:

- The current study was done with a minimum number of subjects with One month and further follow up was not done in the study.
- The outcome variable (Pain scale) used in the study is subjective one.

RECOMMENDATIONS FOR FUTURE STUDY:

- The same study can be conducted on a larger population and longer duration with suitable study design and some objective kind of outcome variables could be included to validate the current results.
- These should include more objective measures for assessment such as colour Doppler ,hormonal changes associated with menstrual pain to explain the possible mechanism of reduction in menstrual pain.
- Other studies can be conducted on subjects with secondary dysmenorrhoea and observed.

8.0 SUMMARY

The objective of this study was to evaluate the effect of cold hip bath on reducing pain and symptoms in primary dysmenorrhoea. The causes of primary dysmenorrhoea are strong uterine contractions which are stimulated

by increased production of the hormone prostaglandin by the lining of the uterus (endometrium). Life style modifications and stress are considered to be important factors contributing to primary dysmenorrhoea in the present generation. Cold hip bath is a procedure which increase the uterine blood circulation and oxygen flow to the uterus, thereby tones the uterine muscles and also increase the peristaltic movements ,improves digestion , appetite and reduce stress.

A total of 85 female subjects were selected to participate in the study based upon the symptoms experienced. All subjects were subjected to pelvic scan to rule out any underlying pathology. Out of 85 subjects 17 had PCOS and were therefore excluded from the study.

After getting informed consent from the patient Menstrual symptom questionnaire(MSQ), Visual analogue Scale (VAS) and will be given for all participants to score dysmenorrhoea-related symptoms. The cold hip bath treatment duration 8 minutes at 55 -65 ° F will be given from the sixth day of menstrual period to the next menstrual cycle. Out of the remaining 68 subjects 8 subjects discontinued with the practice during different time of the study. After intervention (MSQ) and (VAS) was given to analyze the pain and symptoms .

Comparison of Mean within and between the groups were analyzed by paired t test and unpaired t test which is applicable. R statistical software version 3.1.1 was used for the analysis. The results suggested that there was

a significant reduction in the severity of pain and the degree of menstrual cramps along with a reduction in systemic symptoms after one month of the intervention.

There was reduction of mean value of VAS from 8.56 ± 3.23 to 4.60 ± 3.98 within 1 month trial and this shows that cold hip bath has a significant effect ($P < 0.05$) on reduction of pain in primary dysmenorrhoea. The two factor analysis of MSQ during the three months duration also showed that the mean congestive score reduced from 24.56 ± 3.40 to 19.78 ± 3.89 which show a significant reduction ($P = 0.02$) of congestive symptoms. Similarly the spasmodic factors of the subjects also reduced from the mean baseline score 27.80 ± 4.60 to 23.87 ± 7.10 which show a significant reduction ($P = 0.04$) of spasmodic symptoms. Therefore the present study confirms that cold hip bath alone proves to be effective in the reduction of pain and symptoms with primary dysmenorrhoea.

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10.0 ANNEXURES
ANNEXURE 1: CONSENT FORM
INFORMED CONSENT FORM

Title of the study: **“To evaluate the efficacy of cold hip bath on primary dysmenorrhoea”**

Name of the Participant:

Name of the Principal Investigator: Dr. P. PremaLatha

Name of the Institution: Government Yoga and Naturopathy Medical College, Chennai – 106.

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in **“To evaluate the efficacy of cold hip bath on primary dysmenorrhoea”**.

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.
5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.
6. I have been advised about the risks associated with my participation in this study.
7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
8. I have not participated in any research study within the past _____ month(s).

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understood that my identity will be kept confidential if my data are publicly presented.

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature _____

Date _____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature _____

Date _____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

Name Dr. P. PremaLatha Signature _____

Date _____

ஆராய்ச்சி ஒப்புமை படிவம்

ஆராய்ச்சி தலைப்பு:

சூதகவலிக்கு குளிர் இடுப்பு குளியல் அளித்து அதன் செயல்படுத்தும்
திறனை கண்டறியும் மதிப்பீடு

பங்கேற்பாளரின் பெயர்:

வயது :

தேதி:

எண்:

1. இந்த ஆராய்ச்சியில் பிறரின் நிர்வகிப்பின்மீது என் சொந்த விருப்பத்தின் பேரில் நான் இதில் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்து எவ்வேலையும் பின் வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொள்வேன்.
2. நான் ஆராய்ச்சி குறித்த இந்த விவரங்களை கொண்ட தகவல் தாளைப் பெற்றுக்கொண்டேன்.
3. நான் ஏதாவது அசாதாரண அறிகுறிகளை அனுபவித்தால் உடனடியாக முதன்மை ஆராய்ச்சியாளரிடம் தெரிவிப்பேன்.
4. நான் என்னுடைய சுய நினைவுடன் மற்றும் முழு சுதந்திரத்துடன் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள சம்மதிக்கிறேன்
5. நான் இந்த ஆராய்ச்சி சம்பந்தமான பரிசோதனைகளை செய்துகொள்ளவும் மற்றும் சிகிச்சை எடுத்துக்கொள்ளவும் முழு சம்மதம் தெரிவித்துக்கொள்கிறேன்.
6. எந்தவொரு காரணத்திற்காகவும் என் அனுமதியின்றி எந்த நேரத்திலும் ஆய்விலிருந்து என் பங்கேற்பு நீக்கப்படும் என்று எனக்கு தெரியும்.
7. இந்த ஆய்வில் பங்குதாரர்கள் ஒழுங்குமுறை அதிகாரிகள் அரசுக்கு பங்கு அளித்ததன் விளைவாக கிடைத்த தகவலை வெளியிட முதன்மை ஆராய்ச்சியாளருக்கு அனுமதி வழங்கப்படுவதை நான் அறிந்திருக்கிறேன்.

பங்கேற்பாளரின் பெயர் மற்றும் கையொப்பம்:

முதன்மை ஆராய்ச்சியாளர் கையொப்பம்:

(பெயர் மரு.ப.பிரேமலதா)

ANNEXURE 2: MODEL CASE SHEET

GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE,
ARUMBAKKAM, CHENNAI-600106

P.G. DEPARTMENT OF YOGA

PRINCIPAL INVESTIGATOR: Dr.P.Prema latha B.N.Y.S.

HEAD OF DEPARTMENT:

Dr.N.MANAVALAN , N.D (OSM),M.Phil,M.A(G.T); M.Sc (Y&N),

P.G.D.Y; P.G.D.H.M; P.G.D.H.H,

NAME:

O.P.NO:

SEX:

PARTIPITANT NO:

AGE:

DATE:

ADDRESS:

PHONE NO:

OCCUPATION:

MARITAL STATUS:

PRESENT COMPLAINTS:

HISTORY OF PRESENT COMPLAINTS:

PAST HISTORY:

MEDICAL HISTORY:

SURGICAL HISTORY:

FAMILY HISTORY:

OCCUPATIONAL HISTORY:

PERSONAL HISTORY:

Diet:

Appetite:

Digestion:

Bowel Movement:

Micturition:

Sleep:

Exercise:

Addiction:

Allergic to:

ANTHROPOMETRY:

Height:

Weight:

B.M.I.

VITAL DATA:

Respiratory count:

Pulse Rate:

Temperature:

Blood pressure:

MENSTRUAL HISTORY:

Age of menarche:

Last menstrual period:

Menstrual cycle length and frequency:

Heaviness of bleeding:

Intermenstrual bleeding:

Leucorrhoea:

Associated symptoms:

SYSTEMIC EXAMINATION

CARDIOVASCULAR SYSTEM:

RESPIRATORY SYSTEM:

GASTRO-INTESTINAL SYSTEM:

CENTRAL NERVOUS SYSTEM:

ENDOCRINE SYSTEM:

GENITO URINARY SYSTEM:

LOCOMOTOR SYSTEM:

PAST INVESTIGATIONS:

FINAL DIAGNOSIS:

NATUROPATHIC INTERVENTION:

ANNEXURE 3

NAME:

DATE:

O.P. NO:

VISIT NO:

PARTICIPANT CODE:

RATE THE PAIN DURING MENSTRUATION:

--	--	--	--	--	--	--	--	--	--

--

0 1 2 3 4 5 6 7 8 9

10

**No pain
possible**

Moderate pain

Worst

SIGNATURE OF

PARTICIPANT

SIGNATURE OF

PRINCIPAL INVESTIGATOR

ANNEXURE 4

MODIFIED MENSTRUAL SYMPTOM QUESTIONNAIRE

NAME:

DATE:

O.P. NO:

VISIT NO:

PARTICIPANT CODE:

TICK IN THE APPROPRIATE BOX:

		Never	Rarely	Sometim	Often	Always	
	Item	1	2	3	4	5	
1	I feel irritable, easily 'agitated, and am impatient a few days before my period.						
2	I have cramps that begin on the first day of my period.						
3	I feel depressed for several days before my period.						
4	I have abdominal pain or discomfort which begins one day before my period.						
5	For several days before my period I feel exhausted. lethargic or tired.						
6	I only know that my period is coming by looking at the calendar.						
7	I take a prescription drug for the pain during my period.						
8	I feel weak and dizzy during my period.						
9	I feel tense and nervous before my period.						
10	I have diarrhoea during my period.						
11	I have backaches several days before my period.						
12	I take aspirin for the pain during my period.						
13	My breasts feel tender and sore a few days before my period.						

		Never	Rarely	Sometim	Often	Always	
	Item	1	2	3	4	5	
14	My lower back, abdomen. and the inner sides of my thighs begin to hurt or be tender on the first day of my period.						
15	During the first day or so of my period. I feel like curling up in bed. using a hot water bottle on my abdomen, or taking a hot bath.						
16	I gain weight before my period.						
17	I am constipated during my period.						
18	Beginning on the first day of my period, I have pains which may diminish or disappear for several minutes and then reappear.						
19	The pain I have with my period is not intense, but a continuous dull aching.						
20	I have abdominal discomfort for more than one day before my period.						
21	I have backaches which begin the same day as my period.						
22	My abdominal area feels bloated for a few days before my period.						
23	I feel nauseous during the first day or so of my period.						
24	I have headaches for a few days before my period.						

SIGNATURE OF
PARTICIPANT

SIGNATURE OF
PRINCIPAL INVESTIGATOR